October 30, 2013

Marilyn Tavenner
Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244–8016

Re: Concerns about the Palmetto Molecular Diagnostics (MolDX) Services Program and Medicare coverage as well as their impact on Gap Fill Pricing for Molecular Pathology Procedures

Dear Ms. Tavenner:

The undersigned organizations represent over 150,000 medical laboratory professionals engaged in molecular diagnostic testing.

We request a meeting with you to discuss our concerns and recommendations for changes to the Molecular Diagnostic Services Program ("the MolDX program"), Medicare's policy for coverage of molecular diagnostic tests, and the assignment of payment rates to those tests via the "gap filling" process. We are concerned that the actions of Medicare contractors have confused coding, coverage and payment.

Fundamentally, we believe the MolDX program and its extension to other Medicare contractors creates serious concerns about Medicare beneficiaries' access to medically necessary testing used to diagnose disease, identify potential therapies, and monitor the progress of therapy for life-threatening diseases such as breast, colon and lung cancer. Actions taken by some Medicare contractors follow neither the letter nor the spirit of the law, which requires that coverage decisions be transparent and based on medical evidence. Further, we are concerned that Medicare assumes that tests performed primarily in pediatric populations would never have other uses in adults that would be covered by Medicare. This assumption is resulting in

inappropriately denying access to medically indicated testing for younger Medicare beneficiaries who are eligible based on disability status. Yet another consequence is that by not pricing tests that are primarily performed in the pediatric population, some state Medicaid programs are not paying for the appropriate molecular pathology procedures.

MolDX Program Does Not Follow the Coverage Decision Process

We have serious concerns with the MolDX program and the inconsistencies of the program with the established LCD process. The LCD is recognized as 'clear policy' about medical coverage for Medicare beneficiaries. The LCD is to be used for medical review including the initial determinations, development of automatic coverage or denials, and all levels of appeal including Administrative Law Judge (ALJ) reviews as well as program integrity review and audits. The Medicare Program Integrity Manual states in PIM 83 Chapter 13 that an LCD should "specify under what clinical circumstances a service is considered to be reasonable and necessary" and that a contractor "shall"(emphasis by CMS) develop a new or revised LCD when it identifies an item or service that is never covered under certain circumstances.

The Molecular Diagnostics LCD, issued by Palmetto and adopted by Noridian, applies a non-coverage decision to an extremely broad category of tests virtually encompassing all molecular procedures but does not refer to any particular items or services or clinical circumstances under which items and services would be considered "reasonable and necessary." Rather than developing LCDs to set forth its decisions about whether particular items or services are covered, Palmetto has done so in webpage statements published on the MolDX website.

(See details in **Attachment A**: Detailed Explanation of Concerns with the MolDX Program, **Attachment F**: Concerns and Inconsistencies with web page statements, and **Attachment E**: Copies of MolDX Program web pages).

This is counter to the LCD process in that it denies all stakeholders including the public, the medical community, and the CAC the opportunity to comment on the decisions. Critically important, the webpages, unlike Articles, are not posted in the Medicare Coverage Database further complicating claims processing, including automated reviews and potential requests for overpayment (See details in **Attachment C**: Table of Procedures, Support Documents and Effective Dates).

The webpage statements also declare that Palmetto has concluded that the tests in question are "statutorily excluded". We disagree with this conclusion. CMS has specifically stated that the statutory exclusion which prohibits coverage of screening services [based on §1862(a)(7)] applies to services or procedures 'furnished in the absence of signs, symptoms, complaints, or personal history of disease or injury."[i, ii] In our analysis, the reason cited for denying coverage meets the CMS definition of a screening exclusion in only 7 of the 49 statements.

CMS has clarified that the statutory exclusion only applies when a procedure is performed in the asymptomatic person. Use of a test in the symptomatic person is to be considered a diagnostic test. (See **Attachment D**: Statutory Exclusion as the Reason for Denials).

Medicare contractors have broadly interpreted some tests as "screening tests"

without fully examining the indications in which those tests are used, and require physicians to follow clinical guidelines for tests that could be out-of-date. The dual use of the word 'screening' by Medicare as a payer and by physicians and clinical laboratories has resulted in the inappropriate classification of some clinical laboratory procedures as statutory exclusions. Providers do not have the ability to dispute Palmetto's conclusion, as providers are not able to request reconsideration of the decision, as they can for published LCDs.

We are not opposed either to proper Local Coverage Determinations for each of these services, or to an actual National Coverage Determination. What we do oppose, and seek to have rescinded, are 1) the above-described present actions purporting to be LCDs by those administrative contractors which improperly make coverage determinations as above, and 2) those "LCDs" promulgated by other administrative contractors with no substantive content except reference to another contractor's determinations, which generalizes the initial lack of proper process or meaningful consideration to other jurisdictions.

CPT Coding Guidelines Are Not Being Followed

Palmetto has used the local coverage webpage statements to establish its own coding for covered and noncovered tests. Several of our organizations have been and continue to participate in the multi-stakeholder process through the American Medical Association CPT Editorial Panel (in which CMS also has representation,) to design the unique molecular pathology procedure CPT codes. The creation of Unique Test Identifiers by Palmetto fails to recognize that procedures coded using Molecular Pathology Tier 1 or MAAA CPT codes specifically identify the procedure performed. Tests reported by Tier 2 codes can be identified using the analyte, as per Palmetto's Claims Submission Guidelines. Correct coding should recommend their use without having to obtain a separate identification number.

Guidance from the webpage statements also encourages miscoding by disregarding the test-specific molecular pathology CPT codes and instead insisting that tests be billed with "not otherwise classified" codes ("NOC codes"). These include CPT codes 81479 (not otherwise specified molecular procedure) and 84999 (unlisted chemistry procedure codes). In some cases particular tests have been submitted to Palmetto with a decision by them that an NOC code should be used instead of the established CPT code which describes the procedure correctly. In another case, molecular procedures with existing CPT codes that have been performed on the same day are being referred to as a 'panel' and assigned to an NOC code for billing.

These examples are an inappropriate use of the CPT codes, which are a HIPAA-approved code set. Currently there is no way to challenge Palmetto's decision about the proper code to use. Additionally, items and services described by NOC codes are not paid automatically; rather, as Palmetto states on its website, "Each test will be assessed on an individual basis and priced according to the most appropriate method. Palmetto GBA will review the pricing method with the individual lab upon completion of the TA." Currently, there is no way to challenge Palmetto's decision about the correct code to use to submit a molecular pathology test for reimbursement or the

reimbursement level itself. (See details in **Attachment G**: Code Assignment and Identifiers).

The Gap-Filling Process Sets Payments Based on Inappropriate Coverage and Coding

Another serious concern is the way in which Palmetto and other contractors have combined decisions about coverage and payment in their communications about gap-filling. This distorted process of coverage determinations and coding guidelines is being commingled with price setting at what is essentially an arbitrary level of granularity. The MolDX program is distinguishing services not on the basis of any recognized system of nomenclature or coding, but rather on privately supplied supplementary designators, which are used to differentiate among clinically equivalent services which are otherwise identically coded under HIPAA-approved systems of nomenclature. By requiring the use of the NOC code for FDA-approved versions of a test, vs. use of the CPT code for other tests, the median prices that are being used to establish the National Limitation Amounts for the CPT codes are distorted due to the exclusion of the FDA approved version.

Finally, the MolDX program includes rules that create differential pricing between in vitro diagnostic kits that have been approved by the Food and Drug Administration (FDA) and laboratory developed tests (LDTs) that are performed in clinical laboratories under the Clinical Laboratory Improvement Amendments (CLIA.)

We believe that Medicare coverage and payment policy is not the appropriate avenue for addressing perceived concerns about the quality or safety of LDTs. Both of our organizations have experts who would be pleased to help CMS understand emerging technologies in the field, such as so-called Next Generation Sequencing (NGS), that are performed in CLIA certified clinical laboratories.

The MolDX Program Should Not Expand to Other Jurisdictions

Questions about administration of molecular pathology services in jurisdictions other than J1, JE and J11, have been raised with concerns about the specific jurisdictions Palmetto has been or is administering claims based on the MolDX Program. Correct coverage and payment for procedures must be provided to a beneficiary based on the LCDs and instructions in place for that jurisdiction. The providers and beneficiaries in that jurisdiction should be informed if that is not the case and be informed of the dates to which it applies. This should be publicly available for appeals and program integrity issues. Those involved in the medical review and claims adjudication should be available to answer questions.

Ensuring that Medicare beneficiaries have access to innovations in medical science demands that CMS make changes to the MolDX program, particularly if a nationwide expansion of the program is envisioned. Our organizations recommend the following changes to the program be made immediately:

1. Given the program's fundamental flaws and lack of adherence to federal law, CMS regulations and the CPT coding guidelines, we recommend that CMS first restrict Medicare contractors from adopting the MolDX program in jurisdictions

that have not already done so.

2. Require the following of the MolDX program if it is to continue in the Palmetto and Noridian jurisdictions:

    a. Limit the application of statutory exclusion to screening of asymptomatic patients as defined in CLM 104. Chapter 16. Laboratory Services §120.1 and publish an Article to address this non-coverage for statutory exclusion along with the appropriate ICD-9 codes to be submitted.

    b. When 'reasonable and necessary' criteria are cited as the basis for denial of coverage, the MolDX Program should properly describe the reason for denial of services associated with §1862(1)(A) as 'reasonable and necessary' denials. The denial message to the beneficiary should be based on 'reasonable and necessary' criteria.

    c. Medicare should pay claims for molecular pathology tests, unless an LCD exists that specifically states that a test is not covered. If no LCD for a test exists, Medicare should send claims for manual review of whether the test is 'reasonable and necessary' for the individual patient. No Medicare claims should be automatically denied as "statutorily excluded."

3. Revise Palmetto's statement and adjudication of claims to reflect Medicare's position: that even if ordered as a group (profile or panel, molecular pathology tests will be covered based on the coverage status of each component test. Instruct laboratories of the change and request that claims be reviewed for tests performed the same day that have been denied as a panel where one of the tests was not covered. Because re-opening claims is at the MACs discretion, we ask that Palmetto reopen claims and adjudicate each test based on the coverage status of each component test.

4. The MolDX Program should refrain from pursing its Coverage with Evidence Development Process until the authority has been confirmed and the requirements for the process as applied at the local level are defined by CMS, through a transparent process that allows public comment, similar to that used for NCD with CED.

    a. IF CMS intends to have the MACs use the CED process, then we expect that it apply to all services and not just molecular pathology tests.

    b. We would ask that CMS provide national guidance about how the CED process would be applied at the MAC level, beginning with the requirement that an LCD be developed to provide the framework, similar to the NCD at the national level, that it include safeguards for the patient and that it limit interference in the development of the clinical study (e.g. specifying the qualifications of who can help design and implement a CED).

5. Code Assignment and Identifiers: Recognize that Tier 1 and MAAA CPT codes are unique and specific to the respective molecular procedure, that a separate identifier program is not necessary, and that the use of NOC coding is incorrect when there is a specific CPT code. Continue to use the approach delineated in the Claims Submission instructions for identification of the analyte tested with Tier

2 codes using the respective gene identification.

If in fact it is CMS's position that FDA-approved tests are the preferred tests and LDTs should 'disappear', this should be addressed directly by CMS with public input on the issue. If CMS and payers have a concern about the quality of tests being performed, the appropriate bodies to address this are the FDA and CMS through CLIA. It is not the purpose of MACs to address issues within the purview of other national bodies. In addition, they do not have the level of expertise and resources to perform the task.

6. Address the inconsistencies with CMS instructions on coverage and payment for multi-analyte assays which include an algorithmic component (MAAAs) so that Providers are not in conflict with CMS policy and vulnerable to overpayment and/or charges of fraud.

These issues are creating serious confusion and opacity to a process that has functionally worked for determining appropriate coverage for Medicare beneficiaries. We bring this to your attention along with the Regional Offices that oversee the Palmetto and Noridian contracts so that these issues can be rectified and meet the instructions as set by CMS and the statutory requirements.

Thank you for reviewing our comments. We would be pleased to speak with you to discuss these issues in more detail. If you have any questions about these comments, please do not hesitate to contact Mary Williams, Executive Director of AMP, at mwilliams@amp.org or John Scott, Vice President of Advocacy at CAP, at jscott@cap.org.

Sincerely,

[SENT VIA EMAIL]

American College of Medical Genetics and Genomics

American Society of Clinical Laboratory Science

American Society for Clinical Pathology

American Society for Histocompatibility and Immunogenetics (ASHI)

Association for Molecular Pathologists

College of American Pathologists

CC: Marc Hartstein, MPP
Director, Hospital and Ambulatory Payment Group

Louis Jacques, MD
Director, Coverage and Analysis Group

CMS Regional Offices

Medicare Administrative Contractors

Attachments

[i] Negotiated Rulemaking: Coverage and Administrative Policies for Clinical Diagnostic Laboratory Services. Proposed Rule. 65 FR March 10, 2000. Page 13083.
[ii] CLM 104. Chapter 16. Laboratory Services §120.1 Negotiated Rulemaking Implementation. Clarification of the Use of the Term "Screening" or "Screen"

We recognize that the MolDX Program has used the LCD process to develop the 3 published LCDs* that establish some of the fundamentals of the Program, however, as stated multiple times in the MolDX Program web pages, they are making a decision about 'reasonable and necessary criteria' for coverage on each of the tests submitted for registration and assessment. There are 72 local decisions about coverage for over 120 tests that have been posted to the MolDX website which have not gone through the LCD process. These statements meet the definition of an LCD as defined in Section 522 of BIPA and CFR: "*An LCD is a decision by a Medicare administrative contractor (MAC), fiscal intermediary or carrier whether to cover a particular item or service on a MAC-wide, intermediary wide or carrier-wide basis in accordance with Section 1862(a) (1) (A) of the Social Security Act.* ". [PIM 83 §13.1.3[i]] As such, we believe all the local decisions posted on the website are subject to the LCD process. This brings us to our major concerns about the MolDX Program.

The LCD process was established for many reasons including many of the issues this program has created. Importantly, LCDs are used to communicate local decisions about the medical services that will or will not be covered to providers and payers alike, based on the review of the medical literature and standard of care and whether the service meets reasonable and necessary criteria (see supporting documentation). The LCD is recognized as 'clear policy' about medical coverage for Medicare beneficiaries. The LCD is to be used for medical review including the initial determinations, development of automatic coverage or denials, and all levels of appeal including ALJ reviews as well as program integrity review and audits. The manner in which an LCD is developed for a coverage decision is defined in PIM 83 Chapter 13, starting with presentation as a DLCD and using the process defined in PIM 83 Chapter 13.

We have extensively reviewed the MolDX Program information from the website and supporting documents along with the Medicare Manuals and Statutes that are relevant to LCDs and the LCD process and believe that the program fails in several ways including not meeting the standards for LCDs.

1. We believe that the MolDX Program fails to meet the requirements of the LCD process as defined by Medicare, PIM 83 Chapter 13 and, as such, does not replace the requirements for the use of the LCD process for all local coverage determinations. The following address the major issues. We have provided additional comparison of the requirements of the LCD and LCD process and the MolDX process in **Attachment B**.
    A. The Technical Assessment (TA) process and MolDX decision-making about coverage lacks the transparency that the LCD process requires for creating local coverage policy.

       To ensure that LCDs that affect Medicare beneficiaries would not be based solely on the internal review by the MAC, CMS created the LCD process to require public participation in the LCD process in a manner similar to the process used at the national level. Chapter 13 provides specific instructions that require the draft LCD be presented to and involve the medical community and affected public in review and comment, beginning with a public meeting in some cases, presentation to the CAC and a formal Comment and Notice process.

       The TA process involves only Palmetto and the requesting lab. The requesting lab submits its documents for the TA process through the McKesson online tool. The developer/laboratory who has requested the TA is able to comment on the TA report before it is finalized. The public cannot access information on the McKesson site about the evidence documents submitted by the requesting lab or the evidence reviewed. The documents submitted for the Technical Assessment are not publicly available or cited in the final decision.

*Published LCDs: L33541, L33599 and L32288 (for services prior to 09/16/2013 in JE)

The TA process uses Subject Matter Experts (SME) Palmetto has selected 3 SME who are known only to Palmetto, with unknown expertise for the condition, gene/analyte and use under review. The SME review material provided by the requesting laboratory which is known only to Palmetto, with recommendations made by the SME which are known only to Palmetto.

Based on how it functions and what is presented publicly by Palmetto, the TA process used by the MolDX Program to assist it in making coverage decision is an internal review process. There is no public component for the medical community, other laboratories or patients who will be impacted by the decisions.

As Chapter 13 states: *"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."* [PIM 83 §13.7.1 Evidence Supporting LCD]. We believe this statement also applies to recommendations made by an internal review process.

B. The MolDX Program uses an internal Technical Assessment (TA) process to make local coverage determinations for each TA request and then posts the decision on-line on the Program webpage.

The MolDX Program requires that each request for a TA undergo an individual review and coverage determination. The description of the Program and its TA process is very clear and consistent in stating that it is making coverage decisions for each test.

"*Based on the determination for each assay reviewed, Palmetto GBA will publish information to inform the provider community of the following: coverage, coverage with restrictions, non-coverage and coding*" [Source: TA process webpage]

"*All registered procedures are reviewed to validate that each procedure meets the Medicare criteria for coverage.* " [Source: MolDX: Molecular Diagnostic Services Program webpage]

"*The MolDX process includes a review of all submitted requests to determine if the assay is reasonable and necessary and demonstrates improved patient outcomes*." [Source: TA Process webpage]

The decision about whether a procedure or service meets reasonable and necessary criteria and will or will not be covered or not is then posted on a webpage on the MolDX website. There is no opportunity for public (including medical community) review and comment.

C. The MolDX process does not follow the LCD process of presenting local decisions about coverage for a medical procedure as a draft decision to the public, the medical community, and the CAC and providing a Comment and Notice Period as required.

The CAC and the medical community, laboratories, affected patient groups and public do not even know that the procedure and its use in medical practice is under review until Palmetto posts its final decision as a webpage statement on the MolDX website. This leads to uncertainty within the medical community as to which procedures are under consideration, and may lead to extensive duplicative efforts on the parts of multiple entities to simultaneously submit for the same or similar procedures.

*Published LCDs: L33541, L33599 and L32288 (for services prior to 09/16/2013 in JE)

The TA Process has no mechanism by which the medical community, laboratories, patient groups and other affected public can have input into the initial decision or request it be reconsidered.

D. The published LCDs* by Palmetto and Noridian are broad statements completely encompassing all molecular procedures, identifying only a few specific procedures, and as such are insufficient for practical and thorough review of individual procedures.

- The published LCD is not the primary LCD for any individual procedure. It does not contain any clinical information about an individual procedure; no diagnoses or specific genes are identified with their associated ICD-9 codes and HCPCS codes and there is no literature provided that was used to arrive at the coverage decision.

- The published LCDs* specifically state that each procedure must be individually reviewed to determine if it meets Medicare's reasonable and necessary criteria and that a separate coverage decision will be made for each procedure.

- The LCD contains a list of procedures which have been determined to meet reasonable and necessary criteria but the decision about coverage had been made in the past. The individual procedures are only named with an effective date in the past. The LCD is not the primary document that defines their coverage.

E. Problems identified with the current LCDs and the process used to date

i. We believe Palmetto has inappropriately withdrawn coverage through the LCDs for all Tier 1 and Tier 2 tests without providing evidence or a reason for the withdrawal. The original reason cited in the Draft LCD was that they were 'investigational' to which comments were submitted requesting the evidence that supports the decision that all tests that were covered last year and are part of the medical standard of practice have all become investigational this year. The investigational language was removed from the final version; now the coverage is withdrawn without any rationale.

ii. The procedures identified on the list of covered tests have no other LCD to support the coverage determination. The published LCD* is the only LCD that addresses the test; it has none of the coverage criteria or limitations on coverage (.e.g.ICD-9 codes considered to meet 'reasonable and necessary' criteria for claims submission). The details of the criteria that define the limitations on coverage are presented as a webpage statement. This is an issue for claims adjudication and other concerns, which are addressed in more detail in G.

iii. New tests have been added to the list of covered tests (L33599) which were not present in the Draft version.

The final version of L33599 was posted on 09/1/2011. It was then revised on 09/11 with no revision history or reasons for the change. On 9/11, 2 new tests were added to the list of covered tests; they were not presented in the Draft LCD. There has been no information provided in the Draft LCD or Final LCD about the tests, the clinical indications, or the ICD-9 codes. The decision to cover the tests was not presented to the medical community and public for comment. They should not be added to the LCD. As a new decision to cover a procedure,

*Published LCDs: L33541, L33599 and L32288 (for services prior to 09/16/2013 in JE)

they represent a substantial change to the LCD that should be subject to Comment and Notice [PIM 83 13.7.2].

iv. The FDA-approved tests appear to be receiving preferential treatment for inclusion as covered tests in the LCD.
Tests associated with FDA-approved tests assigned an NOC code have been included in the LCD Covered Tests but the CPT codes for the analyte-specific CPT codes have not been included as covered procedures in the LCDs.

- On 04/26/2013, L32288 was in the Notice Period. It was revised to add coverage for Vysis effective in the past.
- On 04/30/2013, L32288 was in the Notice Period. It was revised to add coverage for therascreen KRAS.
- On 05/12/2013, L32288 became effective with all Tier 1 and Tier 2 codes declared not-covered.
- May, 2013: the Claims Submission Guidelines included a column that identified over half of the Tier 1 codes and some of the Tier 2 codes as covered.
- On 06/19/2013, a webpage statement about covering BCR-ABL gene testing was posted. It includes CPT Codes 81205-81208.
- In July, D33599 was released for J11. It again stated that all Tier 1 and Tier 2 codes were not covered. The BCR-ABL analytes and their analyte-specific codes were <u>not</u> identified as covered nor were the analyte-specific codes contained in the Claims Submission Guidelines.
- On 09/1/2013, L33599 was finalized and the Notice period began.
- On 09/11, 2 FDA-approved EGFR tests with retroactive effective dates to 05/14/2013 and 07/12/2013 were added to the final version of L33599 but the analyte-specific CPT code for EGFR was not addressed even though the webpage statements about coverage for the FDA-approved EGFR testing addressed the code.
- On 09/16/2013, L33541 became effective for JE. It states that all Tier 1 and Tier 2 codes are not covered.
- On 09/17, a new webpage statement was posted, Approved Gene Testing that stated the MolDX Program had determined that testing for these analyte-specific genes and their codes met criteria for a covered service. The webpage lists 64 of the 118 Tier 1 codes and 55 analyte-specific tests for Tier 2 as covered. These are the same codes that were identified as covered in the May Claims Submission Guidelines. However, neither L33541 nor L33599 were modified to add coverage for these tests or the BCR-ABL genes; the webpage statements supporting coverage of these CPT codes remain in conflict with the published LCD. The codes remain officially not covered.
(See Section 2.E for a discussion of webpage statements and Attachment E for a copy of the Claims Submission Guidelines, 5/2013.)

F. The use of an internal technical assessment process by the MolDX program does not replace the established requirements that define the LCD and the LCD process.

2. The MolDX Program has posted over 60 coverage decisions affecting over 180 procedures as webpage statements. These statements describe what Palmetto has decided about whether the procedure meets 'reasonable and necessary' criteria and will or will not be covered and what the criteria for coverage will be. This makes them 'local coverage decisions'. We believe Palmetto is using them in claims adjudication

*Published LCDs: L33541, L33599 and L32288 (for services prior to 09/16/2013 in JE)

which has major program implications because the statements are not LCDs and are not 'clear policy'; they have not gone through the LCD process as specified in Chapter 13 and are not entered into the MCD.

A. There are over 60 coverage decisions affecting over 180 procedures that have been posted on the MolDX Program website as individual web pages.

B. These statements about local coverage decisions for specific procedures or services are being made by the MolDX Program via the internal technical assessment process and then posted as statements on-line on their website, outside the published LCDs* and the LCD process.

   They have not followed the LCD process: They do not identify the resources and references that support their Draft decision. They have not been presented as Draft LCDs to the CAC and the public. They have not been distributed to the groups of health professionals and provider organizations that may be affected by the local decision, which includes representatives of the relevant specialty societies and general public, as specified in PIM 83 §13.7.4.1.C. There was no Comment and Notice period of 45 days each.

C. Content of the posted webpage statements and requirements contained in them does meet the CFR definition of an LCD, a local decision about whether a procedure meets reasonable and necessary criteria and will or will not be covered; however, the web page statements do not meet the requirements to be a formal LCD for a number of reasons.
   i. They do not contain all the information required for an LCD. Specifically, they do not provide the references used to arrive at the decision. This is essential for the medical community and public to assess the evidence used and provide additional references to support different criteria or to counter the coverage recommendation.

      i. They are not organized and formatted consistent with the LCD requirements.

      ii. They do not contain a section related to history and revisions.

      iii. They do not follow the instructions regarding effective dates. Many of the statements do not specifically state when the decision is effective. Many, including most of the non-covered tests, post a retroactive effective date for the coverage decisions. The manual instructions are clear that a new local coverage decision cannot be retroactive [PIM 83 §13.7.4]. Restrictions on coverage must also have effective dates at least 45 days in the future. (See **Attachment C**: Table of Procedures, Support Documents, and Effective Dates)

D. Failure to follow the LCD process and to post decisions as webpage statements has serious implications for all decisions.
   i. Procedures that will be covered: It is important that the criteria and diagnoses associated with a procedure be based on the medical literature and advice of the medical community regarding the standard of practice and most current and relevant medical literature.

      We have concerns about the clinical criteria that have been posted for many of the covered tests; we do not believe they adequately define the appropriate cover limitations based on the standard of medical practice, e.g. Corus CAD, Vectra.

*Published LCDs: L33541, L33599 and L32288 (for services prior to 09/16/2013 in JE)

ii. Procedures that have been declared to be 'statutory exclusions'
We believe all the procedures on the non-covered list are the local MAC's (Palmetto) decision about what will be covered and are subject to the LCD requirements. The final statement for all of them is that these procedures will be denied based on 'statutory exclusi**on'.** We disagree with that determination. We highlight our rationale here and have provided *a*dditional support for our position and our requests in **Attachment D**: Statutory Exclusion as the Reason for Denial.

- CMS has specifically stated that the statutory exclusion which prohibits coverage of screening services [based on §1862(a) (7)] applies to services/procedures 'furnished in the absence of signs, symptoms, complaints, or personal history of disease or injury.."[ii, iii] In our analysis, the reason for denying coverage that meets the CMS definition of a screening exclusion was cited in only 7 of the 49 statements. For the remainder, the reason for not covering the test related to 'reasonable and necessary' criteria.
- The dual use of the word 'screening' by Medicare as a payer and by clinical laboratories has resulted in the inappropriate classification of some clinical laboratory procedures as statutory exclusions. CMS has clarified that the exclusion only applies when a procedure is performed in the asymptomatic person. "*If a person is tested to rule out or to confirm a suspected diagnosis because the patient has a sign and/or symptoms, this is considered a diagnostic test, not a screening test*."[CLM 104. §16.120.1]. This applies even if the CPT code descriptor includes the term 'screen'. [65 FR 48 (March 10, 2000), p 13087 Col. 1.]
- Every one of the 49 web page statements contains the following statement:
  Reference: Sec. 1862 (1) (A) Statutory Exclusion covers diagnostic testing "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,…"

  If a service fails to meet criteria to satisfy Sec. 1862(a)(1)(A), it is a reasonable and necessary' denial.

iii. Contractors do not have an option of whether to create an LCD when it comes to decisions not to cover a service/procedure.

> "Contractors shall develop LCDs when they have identified an item or service that is never covered under certain circumstances and wish to establish automated review in the absence of an NCD or coverage provision in an interpretive manual that supports automated review." [PIM 83 §13.4.A. When to Develop New/Revised LCDs}

All 49 procedures on the Non-Covered list should be presented as LCDs following Chapter 13 instructions.

We have identified a number of procedures on the Non-Covered list that are used for testing symptomatic beneficiaries and have adult conditions associated with them that is not recognized by the non-covered statement. If the procedure, the indications and limitations and rationale for the decision were to be presented as a Draft LCD, the medical community, laboratories and affected public would have the opportunity to review the medical evidence used to arrive at the negative decision and present additional medical evidence that addresses the adult conditions and situations in which testing would be reasonable and necessary for the Medicare population, which includes those eligible by age as well as disability status.

*Published LCDs: L33541, L33599 and L32288 (for services prior to 09/16/2013 in JE)

E. Critically important, webpage statements are local decisions about coverage that are not entered into the Medicare Coverage Database. This is important for 3 reasons.
   i. It is a requirement that the MAC enter all local coverage determinations (LCDs) into the Medicare Coverage Database (MCD). [PIM 83 §3.3.2.8]
   ii. The MCD is a centralized way for providers and beneficiaries to access the current policies and coding instructions for their MAC.
   iii. The MCD is a tracking system that identifies the policies and coding instructions that were in place at the time a service was provided. This is important for appeals, ALJ proceedings and program integrity activities. The LCD contains additional information about when it was revised with specific information about what was revised. The previous version of the LCD is retained in the MCD Archive. This is extremely an important for appeals and program integrity activities.

With webpage statements, there is no tracking system to identify when revisions were made, what changes were made and why. There is no way to identify and locate have been withdrawn as well as previous revisions of active statements.

EXAMPLES:

Topic	**Date**	**Posted**		**Change**
		07/08/2013	New posting	
Claim Submission Guidelines (contains information about how to code for billing purposes, what information to enter on the claim, coverage status of code)	Created 05/09/2013 Accessed from website 5/26/2013	Page is listed as being posted on 06/26/2013	Guidelines were posted as separate webpage – 09/25/2013	5/9/2013 version: The coverage status of individual codes was different from the non-covered status in the LCD effective 05/07/13. This is no longer available. New version: CPT Code list –the column does not include coverage status and pricing.
FAQ (Contains information on coding, billing, modifiers)	12/20/2012	Y	09/26/2013 10/03/2013 10/11/2013	Updated page**
		07/08/2013*	09/01/2013*	Change in page
Oncotype DX Colon (C)	06/28/2012	Y	Y	09/19/2013**
OncoCee (NC)	08/07/2012	Y	N	Page no longer available
Oncotype DX Breast (C)	05/08/2013	Y	Y	Updated page: 09/23/2013** 10/10/2013**
PTCH1^	06/25/2013	Y	Y	7/10/2013** Page updated

NC=non-covered C=covered

*Published LCDs: L33541, L33599 and L32288 (for services prior to 09/16/2013 in JE)

*pdf document created from the MolDX Program website of the items posted that day. See **Attachment E**: Copies of MolDX Program web pages
**Page updated. Page does not indicate what changes were made or what the previous date
^This is included on the Covered Tests list but is actually not covered based on the text.

F. The web statements are in conflict with the published LCD.

i. The published LCDs* for Molecular Pathology state that all procedures reported with Tier 1 and Tier 2 codes and NOCs are not covered.

ii. Only a revision of the LCD or a new LCD can change coverage as defined in the LCD. An LCD policy cannot be reversed or changed by medical review or by a statement posted on a website. [CLM 104 Chapter 29 **b**310]

> "*Clinical review judgment by definition is not a process that MACs, CERT, Recovery Auditors and ZPICs can use to override, supersede or disregard a policy requirement. Policies include laws, regulations, the CMS' rulings, manual instructions, and MAC policy articles attached to an LCD or listed in the Medicare Coverage Database, national coverage decisions, and local coverage determinations."* [PIM 83 §3.3.1.3[iv]]

iii. The MolDX Program website has a list of "Covered Tests". There are 22 webpage statements, addressing 76 CPT analyte-specific codes from Tier 1 and 55 analyte-specific procedures from Tier 2 as well as 18 procedures assigned to an NOC.

iv. This is an issue because these webpage statements conflict with the LCD coverage statement. The LCD establishes a non-covered state for all Tier 1, Tier 2 and NOC codes as noted in i.

Each web page states that Palmetto has made the decision that the procedure meets reasonable and necessary criteria (or similar language). For each of the individual procedures, the statement goes on to cite the diagnoses it applies to, the ICD-9 codes, as well as coding instructions. The content of the webpage is essentially a 'local coverage determination' for that procedure, without a list of references and statement of effective date for coverage as defined in Chapter 13. However, it has not gone through the LCD process and is not posted on the MCD. Therefore, it is not an LCD; it is not a published 'local coverage determination' by Medicare's definition of 'clear policy'.

Because it is not an LCD, the decision in the webpage statement that the procedure is covered cannot override the published LCD* that states that all Tier 1 and Tier 2 codes and the listed NOC codes are not covered.

The posting of coverage decisions in conflict with published LCD policy creates a problem for the beneficiary and provider.

G. We recognize the MolDX Program's intention to use the statements as local coverage decisions for claims processing purposes, including automated reviews and potential requests for overpayment, but this is not the normal process and as such is creating confusion and problems with claims review and appeal.

*Published LCDs: L33541, L33599 and L32288 (for services prior to 09/16/2013 in JE)

i. Use of webpage statements to communicate coverage criteria

The published LCDs* contain no specific information, e.g. indications, ICD-9 diagnosis codes or frequency information, about the tests that will be covered. As noted earlier, each lists the tests as covered, based on a previous decision with the publication date cited. The LCD refers the reader to the MolDX website for additional coding and billing information about the covered procedures. This becomes a circular problem:

- The MolDX website does not contain a copy of the LCDs or a page that provides access to active and retired LCDs and to Articles related to the Program, as can be found on the general J11 Part B website. The only LCD in the MCD that relates to the procedures listed as covered is the published LCD*.
- If there is no other primary LCD with the details of coverage including the effective date of coverage, then the only LCD that indicates the test is covered is the published LCD*.
- With no other LCD for the tests listed as covered, the published LCD* becomes the 'primary LCD' for each of the tests. It is the only LCD related to them and as the only LCD it defines the coverage criteria and the effective date for these tests.
- However the published LCDs do not have any coverage criteria defined for these tests or any test, e.g. indications for testing, applicable diagnoses, ICD-9 codes or frequency. This might lead a provider to assume there is no criteria or limitations on coverage except for 2 things:
  i. There is a statement referring the reader to the website for coding and billing guidelines, which implies there are in fact criteria to be found somewhere.
  ii. The published LCDs also have a statement that Palmetto and Noridian expect the developer's indications to be followed. (See Attachment F for our concerns about this requirement).

The only documents on the website are webpage statements for each test. These statements do contain Palmetto's coverage decision and the criteria for coverage, information that should be presented as an LCD. They are not LCDs; however, we assume the webpage statements are being used to develop automated review of claims based on the CPT coding and ICD-9 information contained in the webpage statement and frequency.

This creates a dilemma for the provider and the beneficiary. Even though there is no LCD with the coverage criteria, if the provider wants to have the procedures reimbursed by Medicare, they need to use the information in the webpage statements. However, the webpage statements are not LCDs, are not entered into the MCD and can change at any time and/or be removed, leaving the provider with no documentation of what was in effect at the time a service/procedure was performed for appeals, post-pay review and program integrity activities. It can leave the beneficiary liable for payment after the fact.

This creates a problem for Palmetto for claims review and automated denials. We believe these webpage statements are being used for automated and medical manual review, including the frequency statements. Medical review is bound by the published LCDs and cannot override or ignore them. Automated denials can only be done when there is 'clear policy' which CMS has defined as an LCD. [PIM 83 §3.3.1.3, CLM 104 Chapter 29 §310] This was specifically addressed during the Negotiated Rulemaking process: automated denials based on frequency can only be applied when there is an LMRP (LCD) [42 CFR 410.32(d)(4).

*Published LCDs: L33541, L33599 and L32288 (for services prior to 09/16/2013 in JE)

42 CFR 410.32(4) Automatic denial and manual review. (i) General rule. Except as provided in paragraph (d)(4)(ii) of this section, CMS does not deny a claim for services that exceed utilization parameters without reviewing all relevant documentation that is submitted with the claim (for example, justifications prepared by providers, primary and secondary diagnoses, and copies of medical records).
(ii) Exceptions. CMS may automatically deny a claim without manual review if a national coverage decision or LMRP specifies the circumstances under which the service is denied, or the service is specifically excluded from Medicare coverage by law.

ii. Use of webpage statements to communicate coding and medical review-related billing and claims submission information

- We recognize MACs can provide information via their website, in educational/training classes and newsletters. As Chapter 3 states, the MACs have the discretion to

  "*publish articles communicating certain information to providers, such as any newly developed educational materials, coding instructions or clarification of existing medical review related billing or claims policy. The MACs are required to enter articles that address LCDs, coding or medical review-related billing and claims considerations into the Medicare Coverage Database (MCD). … All newly created articles shall be posted on the MAC's Web site where duplicate copies can be obtained by providers/suppliers.* (Source: PIM 83 §3.3.2.8)

- Presenting coding and billing guidance as webpage statements creates the same problem as described for LCDs and coverage criteria. The provider is accountable for information contained in an Article but not for web pages. There is no tracking system to identify what statement was in effect at the time the service was provided or the claim processed. There is no system to identify changes in instructions.

  EXAMPLE:
  A document on Claims Submission requirements created on 05/09/2013 was accessed on 05/26/2013, as a pdf from a webpage. It was posted on the MolDX website page which is listed as 06/26/2013 in page captured on 07/08/2013. The document contained important detailed information about how to submit claims for each of the Molecular Pathology codes, including what to enter in the narrative box for each code and the coverage status of each code. These instructions were not posted as an Article and entered into the MCD.

  A new Claims Submission webpage was posted on 09/25/2013 with different information. It is not presented as an Article and entered into the MCD. The document created on 05/08.2013 is no longer available on the website.

*Published LCDs: L33541, L33599 and L32288 (for services prior to 09/16/2013 in JE)

The failure to provide coding and billing information that will be used in medical review as an Article entered into the MCD creates a problem for the provider who is watching the MCD for new material on coverage and coding guidelines.

It raises a major question about information that is not 'clear policy' is being used by Palmetto for claims processing. Despite these concerns, if the provider does not follow the information in the unofficial webpage, they will not have their procedures reimbursed. However, if they do follow a webpage instruction and that instruction is replaced, if there is a question on post-payment review, the provider has no documentation/evidence to support a position that they were following MAC instructions.

H. These webpage statements are NOT LCDs and are being used inappropriately to adjudicate claims. There are statements related to claims adjudication that are inconsistent with Medicare instructions. We address the following in detail in **Attachment F:** Concerns and Inconsistencies with web page statements.
   i. Multiple, inconsistent effective dates
   ii. Panels – denial of an entire panel when one of the procedures is not covered
   iii. Requiring that the providers use the procedure developers indications for a procedure
   iv. Instructions to present additional medical information to obtain an individual coverage decision on appeal for a procedure they have declared to be a 'statutory exclusion'.
   v. Code assignment using –GA modifier
   vi. Inconsistent information about use of modifiers
   vii. Lack of clear denial reasons and claim resubmission instructions
   viii. Use of the CED process at the MAC level

3. Concern with the coding assignment and creation of Unique Identifiers (UI).
Procedures that can be coded using Tier 1 or MAAA codes are uniquely identified and correct coding should recommend their use without having to obtain a UI number and should not be assigned to the 81479 "not otherwise specified molecular procedure" code.

   We have provided examples of inappropriate use of the codes and NOC codes to report procedures for which specific codes are available. (**Attachment G**: Code Assignment and Identifiers)

   a. Creation of a panel to be billed under an NOC
      i. Combining all procedures under 1 NOC when all procedures have a specific CPT code
      ii. Combining all procedures under 1 NOC when only 1 of the procedures does not have a specific NOC
      iii. Combining all procedures under 1 NOC when at least 1 procedure has a specific CPT code
   b. Assigning tests to be billed using an analyte-specific CPT code that does not match the description of the test being performed
   c. Assigning an NOC code to an FDA-approved test and the analyte-specific CPT code to the LDT tests for the same gene/analyte-specific test
   d. Use of the NOC code from another section to cover and pay for MAAA
   e. Implications of coding instructions on the payment and fee schedule

4. Administration of molecular pathology services in jurisdictions other than J1, JE and J11.
   The question has been raised about what areas/jurisdictions/MACs Palmetto has been/is administering claims based on the MolDX Program, with the exception of the requirement for a Unique Identifier.

*Published LCDs: L33541, L33599 and L32288 (for services prior to 09/16/2013 in JE)

The Claims Submission Guidelines raise the question of what other areas Palmetto is administering. *"As per the MolDX Program, claims submitted in JE without a unique ID will be denied. Claims submitted in all other areas administered through Palmetto GBA…"* [Source: MolDX: MoPath Claims Submission Guidelines, page updated 09/25/2013. The same language with reference to J1 is included in the 05/26/2013 Claims Submission instructions.

We have been informed by lab personnel in other jurisdictions that their claims had been processed by Palmetto and the local MAC was not able to help explain claim denials.

It is important that coverage and payment for procedures provided to a beneficiary be based on the LCDs and instructions in place for that jurisdiction. The providers and beneficiaries in that jurisdiction should be informed if that is not the case and the dates to which it applies. This should be publicly available for appeals and program integrity issues. Those involved in the medical review and claims adjudication should be available to answer questions. Furthermore, laboratories which are outside of Palmetto jurisdiction were not given the opportunity to participate in any open comment periods or solicited regarding costing, therefore these laboratories are being subjected to coverage decisions and payment levels which were not specific to their locality, which specifically violates the LCD process and the Gapfill process requirements.

[i] References the section in PIM 83, Chapter 13 The LCD Process

[ii] Negotiated Rulemaking: Coverage and Administrative Policies for Clinical Diagnostic Laboratory Services. Proposed Rule. 65 FR March 10, 2000. Page 13083.

[iii] CLM 104. Chapter 16. Laboratory Services §120.1 Negotiated Rulemaking Implementation. Clarification of the Use of the Term "Screening" or "Screen"

[iv] References the Section in PIM 83, Chapter 3, Verifying Potential Errors and Taking Corrective Actions

*Published LCDs: L33541, L33599 and L32288 (for services prior to 09/16/2013 in JE)

Attachment B: Differences between the TA Process and LCD Process

This document highlights some of the differences between the decision-making which includes the TA process used by the MolDX Program and the LCD Process as defined by CMS in PIM Chapter 13.

These are additional differences between the TA process and the LCD process that have not been already addressed in Attachment A: Details

Differences between the 2 processes	Palmetto MolDX - TA Process	LCD Process
Criteria	o **Criteria /evidence to determine coverage for clinical utility**: TA process includes assessment of cost and cost effectiveness in determining coverage. ▪ *If the clinical utility and economic data are in the public domain (published), SME will review it. If it is proprietary, then Palmetto GBA will review it."* [FAQ/TA Section/Q13] ▪ "*The program defines a clear, evidence-based process to ensure clinical quality, manage molecular diagnostic services, and measure the impact they have on cost and care."* [MDSP] ▪ "*Demonstrates improved patient outcomes or changed physician treatment behavior"* [TAP] o *Uses the CMTP document on clinical validity and utility to guide coverage decisions (Public presentation, 10/22/2013 per Dr. Jeter)*	➢ The LCDs specify under what clinical circumstances an item or service is considered to be reasonable and necessary." [**§**13.1.3} ➢ Criteria: Cost is not one of the criteria in determining whether a service meets 'reasonable and necessary' • Safe, effective, not investigational, *meets but does not exceed patient's medical needs, at least as beneficial as an existing and available medically appropriate alternative* [§13.5.1] • Consideration of alternates as a prerequisite, specifically states that the prerequisites are to be based on 'medical appropriateness, not on cost effectiveness.' [§13.5.4] • "Effective' This is applied to the service. It is not restricted or defined further.
Reasons for initiating	o **Request of lab for unique identifier for each lab test performed** "*The MolDX process includes a review of all submitted requests to determine if the assay is reasonable and necessary and demonstrates improved patient outcomes*." [TAP]	➢ When a service has been identified that will never be covered ➢ To address a validated problem that's a risk to the trust fund ➢ To assure beneficiary access [**§**13.4
Evidence	o **Who provides the evidence:** *"The onus is on the laboratory provider to make their best case using any and all evidence to support clinical utility*" [FAQ/TA/Q2] o **Amount of evidence** ▪ 2 published articles to support clinical utility [FAQ/TA/Q2] ▪ *The SME will only have access to the scientific literature submitted with the TA* [FAQ/TA/Q4]	➢ "Initial action in gathering evidence…shall always be a search of the published scientific literature.." [**§**13.7.1 ➢ LCD should be based on: • *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*

MDSP = Molecular Diagnostic Services Program, last updated 09/22/2013
TA = Technical Assessment webpage, last updated 08/23/2013. Accessed 09/23/2013
FAQ = Frequently Asked Questions, last updated 09/26/2013

Attachment B: Differences between the TA Process and LCD Process

Differences between the 2 processes	Palmetto MolDX - TA Process	LCD Process
		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* ➢ *LCDs which challenge the standard of practice in a community and specify that an item or service is never reasonable and necessary shall be based on sufficient evidence to convincingly refute evidence presented in support of coverage*. [**§**13.7.1
Accountability	None	➢ DLCD and copy of the CAC minutes sent to RO within 10 days of CAC meeting [**§**13.8.1.4.I] ➢ MACs shall post to webisite a summary of comments received with contractors's response, prior to or on the start date of the notice period, which is to remain visible for at least 6 months [13.7.4.2.]
Reconsideration	TA process for review of a non-covered decision: request for review can be made "a new request includes substantive new information that was not included in the initial request, the lab may submit anew request six months after the non-coverage determination was issued." [FAQ/TA/Q8]	➢ LCD requires the MAC to consider all reconsideration requests for a change in the LCD if they are submitted by a beneficiary/business in the jurisdiction with no restrictions on time or evidence. [**§13.11]**

MDSP = Molecular Diagnostic Services Program, last updated 09/22/2013
TA = Technical Assessment webpage, last updated 08/23/2013. Accessed 09/23/2013
FAQ = Frequently Asked Questions, last updated 09/26/2013

MolDX Program – Tests on the "Covered Tests" List

The published LCDs refer to other publications which support the coverage decision for the tests listed as covered. We searched the MCD to identify all LCDs or Articles, current and archived, related to the topic and the tests cited in the published LCDs to identify support/primary documents.

Covered Test	Jurisdiction	LCD	LCD Effective Date	LCD: Published date cited for test	LCD: Effective date cited for test	Article	Article Effective Date	Other Effective Date cited in Article	Web page Date posted	Web page statement: "Effective for DOS on or after…
Afirma+	J1-E	L33541 L32288	09/16/2013 05/07/2012	10/31/12*	01/01/2012	A51697	03/05/2012 RETIRED	01/01/2012 RETIRED	03/05/2012	01/01/2012+
	J11	L33599	10/18/2013	10/31/12*	01/01/2012	None	N/A	N/A		
Allomap+	J1-E	L33541 L32288	09/16/2013 05/07/2012	10/31/12*	02/28/12**	A51694	03/01/2012 RETIRED	None	03/07/2012	None
	J11	L33599	10/18/2013	10/31/12*	02/28/12**	None	N/A	N/A		
Approved Gene Testing	J1-E-E	None	N/A	N/A	N/A	None	N/A	N/A	09/17/2013	None
	J11	None	N/A	N/A	N/A	None	N/A	N/A	09/17/2013	None
Avise PG+	J1-E-E	L33541 L32288	09/16/2013 05/07/2012	10/31/12*	04/25/2012	A51838	05/12/2012 RETIRED	None	05/24/2012	5/12/2012+
	J11	L33599	10/18/2013	10/31/12*	04/25/2012	A51838	5/12/2012 RETIRED	None		
BCR-ABL+	J1-E-E	None	N/A	N/A	N/A	None	N/A	N/A	06/19/2013	04/15/2013+
	J11	None	N/A	N/A	N/A	None	N/A	N/A	06/19/2013	04/15/2013+

RETIRED: Articles in J1 alone and those published jointly with J11 were retired with the change in MACs effective 09/16/2013.
Shaded = Article is still active

+ Effective date is retroactive, before the publication date of the Article or webpage statement, whichever is earlier.

*The LCD previous publications for the 'published date' and the 'effective date'. No document was identified that was published 10/31/2013 in the MCD (current and archived) or the MolDX website. The 1st draft of L32288 was released sometime in 2012 but the archived version is not dated 10/31/2012.

**LCD marking – "indicates test specific retired/active LCD coverage prior to identifier assignment."

*** Webpage contains additional information not contained in the Article posted on MCD.

MolDX Program – Tests on the "Covered Tests" List

Covered Test	Jurisdiction	LCD	LCD Effective Date	LCD: Published date cited for test	LCD: Effective date cited for test	Article	Article Effective Date	Other Effective Date cited in Article	Web page Date posted	Web page statement: "Effective for DOS on or after…
Cancer type ID[+]	J1-E	L33541 L32288	09/16/2013 05/07/2012	10/31/12*	07/25/2011**	A51801	04/23/2012 RETIRED	None	2/21/2013	11/19/2012[+]
	J11	L33599	10/18/2013	10/31/12*	07/25/2011**	A51801	04/23/2012 RETIRED	None		
CellSearch	J1-E	None	N/A	N/A	N/A	None	N/A	N/A	03/19/2013	None
	J11	None	N/A	N/A	N/A	None	N/A	N/A	03/19/2013	None
Chimerism	J1-E	None	N/A	N/A	N/A	None	N/A	N/A	9/19/2013	None
	J11	None	N/A	N/A	N/A	None	N/A	N/A	9/19/2013	None
cobas BRAF V600[+]	J1-E	L33541 L32288	09/16/2013 05/07/2012	10/31/12*	09/07/2012	A51962	09/07/2012 RETIRED	None	09/07/2012	None
	J11	L33599	10/18/2013	10/31/12*	09/07/2012	A51965	09/07/2012	None		
cobas EGFR[+]	J1-E	L33599 Added to final version on 09/11	10/18/2013	09/11/2013	05/14/2013	None	N/A	N/A	9/11/2013	5/14/2013[+]
	J11	None	N/A	N/A	N/A	None	N/A	N/A		

RETIRED: Articles in J1 alone and those published jointly with J11 were retired with the change in MACs effective 09/16/2013.
Shaded = Article is still active

[+] Effective date is retroactive, before the publication date of the Article or webpage statement, whichever is earlier.

*The LCD previous publications for the 'published date' and the 'effective date'. No document was identified that was published 10/31/2013 in the MCD (current and archived) or the MolDX website. The 1st draft of L32288 was released sometime in 2012 but the archived version is not dated 10/31/2012.

**LCD marking – "indicates test specific retired/active LCD coverage prior to identifier assignment."

*** Webpage contains additional information not contained in the Article posted on MCD.

MolDX Program – Tests on the "Covered Tests" List

Covered Test	Jurisdiction	LCD	LCD Effective Date	LCD: Published date cited for test	LCD: Effective date cited for test	Article	Article Effective Date	Other Effective Date cited in Article	Web page Date posted	Web page statement: "Effective for DOS on or after…"
Corus CAD[+]	J1-E	L33541 L32288	09/16/2013 05/07/2012	10/31/12*	01/01/2012	A51923	08/08/2012 RETIRED	Effective 01/01/2012 RETIRED	08/07/2012	01/01/2012[+]
	J11	L33599	10/18/2013	10/31/12*	01/01/2012	A51927	08/08/2012	Effective 01/01/2012		
HERmark	J1-E	L33541 L32288	09/16/2013 05/07/2012	10/31/12*	12/09/2011	A51599	12/09/2011 RETIRED	Effective 12/09/2011 RETIRED	04/23/2012	12/9/2011[+]
	J11	L33599	10/18/2013	10/31/12*	12/09/2011	A51599	12/09/2011 RETIRED	Effective 12/9/11		
MammaPrint	J1-E	L33541 L32288	09/16/2013 05/07/2012	10/31/12*	11/16/09**	A51703	03/08/2013 RETIRED	None	03/12/2013	None
	J11	L33599	10/18/2013	10/31/12*	11/16/09**	No	No	N/A		
Oncotype DX Breast	J1-E	L33541 L32288	09/16/2013 05/07/2012	10/31/12*	09/02/08**	A51727	03/20/2012 RETIRED	None	5/08/2013** Updated page posted 10/10/2013*** with new information	None
	J11	L33599	10/18/2013	10/31/12*	09/02/08**	A51726	03/20/2012 Updated 05/07/2013	None		
Oncotype DX	J1-E	L33541 L32288	09/16/2013 05/07/2012	10/31/12*	03/26/2012	A51725	3/20/2012 RETIRED	None	06/28/2013***	None

RETIRED: Articles in J1 alone and those published jointly with J11 were retired with the change in MACs effective 09/16/2013.
Shaded = Article is still active

[+] Effective date is retroactive, before the publication date of the Article or webpage statement, whichever is earlier.

*The LCD previous publications for the 'published date' and the 'effective date'. No document was identified that was published 10/31/2013 in the MCD (current and archived) or the MolDX website. The 1st draft of L32288 was released sometime in 2012 but the archived version is not dated 10/31/2012.

**LCD marking – "indicates test specific retired/active LCD coverage prior to identifier assignment."

*** Webpage contains additional information not contained in the Article posted on MCD.

MolDX Program – Tests on the "Covered Tests" List

Covered Test	Jurisdiction	LCD	LCD Effective Date	LCD: Published date cited for test	LCD: Effective date cited for test	Article	Article Effective Date	Other Effective Date cited in Article	Web page Date posted	Web page statement: "Effective for DOS on or after…"
Colon	J11	L33599	10/18/2013	10/31/12*	03/26/2012	A51724	3/20/2012	None	Updated page posted 09/19/2013	
Progrensa	J1-E	L33541 L32288	09/16/2013 05/07/2012	10/31/12*	05/07/2012	A51963	None	N/A	09/11/2012	09/11/2012
	J11	L33599	10/18/2013	10/31/12*	05/07/2012	A51964	None	N/A		
therascreen EGFR[+]	J1-E	None	None	09/11/2013	07/12/2013	None	N/A	N/A	09/12/2013	07/12/2013[+]
	J11	L33599 Added to final version on 09/11	10/18/2013	N/A	N/A	None	N/A	N/A		
therascreen KRAS	J1-E	L32288- added to LCD on 04/30/2013 L33541	05/12/2012 10/18/2013	04/30/2013	04/30/13	A52215	04/30/2013 RETIRED	N/A	4/29/2013	None
	J11			4/30/2013	04/30/13	None	N/A	N/A		
Tissue of Origin[+]	J1-E	L32120	RETIRED RETIRED	10/31/12* 09.15.2013	07/25/11**	A51800	04.23.2012 RETIRED	None	04/26/2012	04/26/2012

RETIRED: Articles in J1 alone and those published jointly with J11 were retired with the change in MACs effective 09/16/2013.
Shaded = Article is still active

[+] Effective date is retroactive, before the publication date of the Article or webpage statement, whichever is earlier.

*The LCD previous publications for the 'published date' and the 'effective date'. No document was identified that was published 10/31/2013 in the MCD (current and archived) or the MolDX website. The 1st draft of L32288 was released sometime in 2012 but the archived version is not dated 10/31/2012.

**LCD marking – "indicates test specific retired/active LCD coverage prior to identifier assignment."

*** Webpage contains additional information not contained in the Article posted on MCD.

MolDX Program – Tests on the "Covered Tests" List

Covered Test	Jurisdiction	LCD	LCD Effective Date	LCD: Published date cited for test	LCD: Effective date cited for test	Article	Article Effective Date	Other Effective Date cited in Article	Web page Date posted	Web page statement: "Effective for DOS on or after…"
		L32288								
	J11	L32120	RETIRED	05/7/2012	07/25/11*	A51800	04.23.2012 RETIRED	None		
Vectra[+]	J1-E	L32288- test added to LCD 05/10/2013 L33541	05/12/2012 10/18/2013	05/10/2013	06/30/2012	A52227	05.10.2013 RETIRED	Effective for dates of service on and after 04/11/13	07/02/2013	06/30/2012[+]
	J11			5/10/2013	06/30/2012	None	N/A	N/A		
Vysis	J1-E	L32288- added to LCD on 04/26/2013 L33541	05/12/2012 09/16/2013	04/29/2013	08/27/2011	A52070	08/11/2011	Effective 8/27/2011	12/12/2012	08/27/2011
	J11	L33599	10/18/2013	4/29/2013*	08/27/2011	None	N/A	N/A		

RETIRED: Articles in J1 alone and those published jointly with J11 were retired with the change in MACs effective 09/16/2013.
Shaded = Article is still active

[+] Effective date is retroactive, before the publication date of the Article or webpage statement, whichever is earlier.

*The LCD previous publications for the 'published date' and the 'effective date'. No document was identified that was published 10/31/2013 in the MCD (current and archived) or the MolDX website. The 1st draft of L32288 was released sometime in 2012 but the archived version is not dated 10/31/2012.

**LCD marking – "indicates test specific retired/active LCD coverage prior to identifier assignment."

*** Webpage contains additional information not contained in the Article posted on MCD.

ATTACHMENT C: Table of Procedures, Support Documents, and Effective Dates

MolDX Program – List of Non-Covered Tests

^Retroactive effective date

Non-Covered Test - Title	CPT code	Date posted on website & "Last updated" date	Web page -"Effective for DOS"
LPA-Intron 25		01/07/2013	None stated
MyPAP	84999	07/25/2013	None stated
Know Error	84999	07/24/2013	None stated
4Q25-AF Risk Genotype Test		01/07/2013	None stated
9P21 Genotype	83891	01/07/2013	None stated
APOE Genotesting		01/07/2013	None stated
ARVD/C Arrhythmogenic RV Dysplasia / Cardiomyopathy	81479	02/07/2013	on and after February 7, 2013.
Aspartoacyclase 2 deficiency	81200	02/07/2013	on and after February 7, 2013.
ATP7B	81406	7/24/2013	on or after 07/24/2013
BCKDHB	81205	02/07/2013	on and after February 7, 2013.
BLM	81209	7/30/2013	on and after July 30, 2013
BluePrint		01/07/2013	01/07/2013
LPA-Aspirin Genotype		1/07/2013	None stated
CFTR Gene^	81220, 81221, 81222, 81223, 81224	2/05/2013^	on and after January 1, 2013.^
CHD7	81479	06/25/2013	on and after June 26, 2013.
Biocept - OncoCee	88313, 88346, 88361	8/7/2012	None stated
CYP2B6	81404	07/10/2013	None stated
CYP2C9 and/or VKORC1 testing	81227, 81355	06/05/2013	Effective date for this article is January 1, 2013, and not the publication date.
Cytogenomic Constitutional Micrarray Analysis	81228, 81229	1/2/2013	None stated
ENG and ACVRL1 Gene Tests Coding and Billing Guidelines		09/11/2013	None stated
FANCC	81242	02/6/2013	on and after February 6, 2013.
Fragile X^	81243, 81244	1/31/2013^	on and after January 1, 2013.^
GBA	81251	07/30/2013	on and after 07/30/2013
HAX1	81479	2/6/2013	on and after February 6, 2013.
HBB full gene^	81401, 81403-HBB, 81404-	06/24/2013^	on and after May 3, 2013.^

ATTACHMENT C: Table of Procedures, Support Documents, and Effective Dates

MolDX Program – List of Non-Covered Tests

^Retroactive effective date

Non-Covered Test - Title	CPT code	Date posted on website & "Last updated" date	Web page -"Effective for DOS"
	HBB, 81479		
HEXA	81255	2/07/22013	on and after February 7, 2013
HTTLPR	81479	6/25/2013	on and after June 26, 2013.
IKBKAP	81260	2/7/2013	on and after February 7, 2013.
KIF6 Genotype	appropriate code stack	01/07.2013	None stated
L1CAM gene	81479	1/29/2013	on and after January 29, 2013.
Pervenio Lung RS Assay	84999	01/07/2013	None stated
MCOLN1	81290	02/06/2013	on and after February 6, 2013.
MECP2	81302, 81303, 81304	02/19/2013	on and after February 19, 2013.
Mitochondrial Nuclear Gene		01/29/2013	on and after January 29, 2013.
MMACHC	81479	7/10/2013	None stated
MPL	81479 -2013; 81404 effective 1/1/2014	06/25/2013	on and after June 25, 2013.
NSD1	81405-NSD1, 81406-NSD1, 81479	06/25/2013	on and after June 26, 2013.
PAX6 Gene sequencing and deletion/duplication	81479 effective 1/1/2013	01/29/2013	on and after January 29, 2013.
PIK3CA	81479	06/28/2013	on and after June 28, 2013.
PreDX - Tethys Bioscience	84999	01/07/2013	None Stated
PTCH1	81479	First posted: 6/25/2013 Last updated: 07/10/2013	on and after June 26, 2013.
RPS19	81479	6/25/2013	on and after June 25, 2013.
Septin 9 methylated DNA	81401-SEPT9	12/21/2012	None stated
SLCO1B1	83891	01/07/2013	None stated
SMPD1	81330	02/07/2013	02/07/2013
STAT3	81479	6/26/2013	on and after June 26, 2013.
TERC	81479	06/25/2013	on and after June 25, 2013.
TP53	81404, 81405	06/24/2013	on and after June 24, 2013.
UGT1A1	81350	02/27/2013	None stated

Attachment D: Statutory Exclusion as the Reason for Denial

There have been a total of 49 web page statements for tests/services that are non-covered.[i] We believe that Palmetto has incorrectly assigned all its local decisions about these tests to the 'statutory exclusion' category. As 'statutory exclusions' they are not required to go through the LCD process. However, we believe the declaration that they are all 'statutory exclusions' has been made in error. We raise this for 2 reasons: the first is that identifying the correct reason for denial is important because a) there are no exceptions to statutory exclusions, unless they are stated in the statute or they are changed by statute, b) a denial by statutory exclusion cannot be appealed; they are "not covered by Medicare under any circumstances"[ii] which means no amount of clinical evidence can change a statutory exclusion to a covered status for an individual, c) statutory exclusions are not the subject of LCDs as already stated and d) beneficiary's should be notified that they will have to pay for the test, even though waiver of liability does not technically apply. The second reason related to clinical concerns and beneficiary access to medically indicated testing. We will address the reason for denial first.

I. Reason cited for denial of procedures

We have reviewed CLM 104 Laboratory Services and the Negotiated Rulemaking Final Rule[iii] which addresses coverage for 23 clinical lab tests and provided guidance on how CMS determines use of tests that would be a statutory exclusion and diagnostic use of tests that can be covered as 'reasonable and necessary', including the use of ICD-9 codes to distinguish between the two. We have reviewed the webpage statements and 3 reasons given to deny coverage: 1) there is no benefit category, 2) it is a statutory exclusion and/or 3) there is insufficient evidence to support 'reasonable and necessary' criteria. The final statement for each of the tests is that the test will be denied as a 'statutory exclusion'. We believe that in the vast majority of statements, the reason cited is 'reasonable and necessary' criteria.

Our assessment of the reasons given for denial of coverage:

A. Statements of denial: that there is no benefit category for some of the molecular diagnostic tests.

The Non-Covered Tests webpage listing begins with the following statement:

"The following test types are not considered a Medicare benefit and therefore will be denied coverage:"

We believe this statement is not supported by existing statute and current statutory authority as described by CMS in the Negotiated Rulemaking[iv] as well as manual instructions.[v,vi] As a subset of clinical laboratory tests, there is a benefit category for molecular pathology services/tests:

- The first benefit listed for Part B is medical and other health services §1832(a)(1); it specifies physicians services §1832(a)(B)(I).
- "Medical and other health services" are defined in §1861(s); they include physician services (q) and diagnostic services (§1861(s)(2)(C).
- There are no restrictions in these sections that would apply to molecular pathology tests.

Therefore, as services provided by physicians and as a subset of diagnostic services and clinical laboratory tests, there is a benefit category for molecular pathology tests. Some of the tests cannot be singled out as not having a benefit category. It is the use of the test and its relationship to 1862(a)(1)(A) that determines whether an individual test will be covered or not, e.g. when its use for the individual person meets the 'reasonable and necessary' criteria. Statements that there is no benefit category should be removed from all LCDs and website documents.

B. Rationale provided for why the tests will be denied as "Statutory Exclusions".
In the rulemaking document, CMS restated its position that the statutory exclusion of screening services is based on 1862(a)(7). [vii,viii] This text was applied to the 23 clinical lab tests addressed in the document: "*Tests for screening purposes that are performed in the absence of signs, symptoms, complaints, or personal history of disease or injury are not covered except as explicitly authorized by statute*." [ix]

Similar text is found in the CLM on Laboratory Services: "*Tests that are performed in the absence of signs, symptoms, complaints, personal history of disease, or injury are not covered except when there is a statutory provision that explicitly covers tests for screening as described*."[x]

We have reviewed the narrative on the web page statements to determine whether the statutory exclusion criteria cited by CMS has been used to declare the tests non-covered. We found the following:

- Testing the asymptomatic person is the reason cited for not covering the tests in 7 of the 49 statements.
- Three of the tests could be only used in risk assessment but the narrative is not clear.
- For 37 of the tests that have been posted as non-covered, the reason cited in the text is related to the use of the test in diagnosing a condition in the symptomatic patient or the combination of use for diagnosis and for screening the asymptomatic relative.

Reason for non-coverage as cited on the web page	#	Tests^
Absence of signs and symptoms^	3	Cytogenomic Constitutional Microarray, Fragile X, Septin9 methylated DNA
Only use is risk assessment: e.g. parents at risk, related to conceiving a child^	4	ASPA, BCKDHB, CFTR, TERC
Possible use is limited to risk assessment; evidence doesn't support reasonable and necessary use	3	4Q25-AF; LPA-Intron 25, APOE,
'insufficient evidence to support clinical utility' 'insufficient evidence to support the required clinical utility', 'insufficient evidence to support reasonable and necessary criteria"	16	9P21, Biocept-OncoCee, Blueprint, CYP2B6, HTTLPR, KIF6, MMACHC, Mitochondrial nuclear gene, PAX6, Pervenio Lung RS Assay, PIK3CA, PreDX Diabetes Risk Score, Prostate Molecular Markers (HOXD3, PTEN, ERG), SLCO1B1, UGT1A1, VEGFR2
Statutory exclusion but approval on case by case basis on appeal	2^^	ENG/ACVRL1, LPA-Aspirin
Alternate methods to make the diagnosis	6	ATP7B, BLM, ENG/ACVRL1, MPL, PTCH1, STAT3*
Used to confirm a diagnosis	4	ARVD/C, GBA, MECP2**, SMPD1**
Confirm diagnosis in symptomatic and provide recurrence risk, screen for carrier status	3	L1Cam, MCOLN1, NSD1
"Diagnostic to confirm clinical findings', screening in other uses in adults	2	FANCC, IKBKAP
Condition diagnosed another way, screening for parents	1	HEXA

Reason for non-coverage as cited on the web page	#	Tests^
Two conditions associated with gene, 1 only use is related to reproductive risk, other 'not change medical management'	1	HAX1
Diagnostic but usually is diagnosed 'prior to Medicare eligibility' or symptoms and diagnosis occur prior to Medicare eligibility	4	CHD7, HBB, RPS19, TP53

^ These are the reasons as cited by Palmetto. We do not agree that this is accurate.
^^ This is informational. The tests are only counted once, in the primary reason for denial
* Rationale – 'genetic confirmation does not change management'
** Patient may be child for diagnosis; it would be screening in adult

C. Reference cited to support the statement on the web page.
The webpage describing the decision on all 49 web pages includes the following text at the bottom of the webpage:

Reference: Sec. 1862 (1)(A) Statutory Exclusion covers diagnostic testing "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,…"

If the denial is related to reasonable and necessary criteria as required by §1862(1)(A), then it is a reasonable and necessary denial. There are specific instructions in the manual that state that failure to meet Sec. 1862(a)(1)(A) are NOT statutory exclusions, they are 'reasonable and necessary' denials.

D. The dual use of the word 'screening' by Medicare as a payer and by clinical laboratories
The different use of the term 'screening' has resulted in the inappropriate classification of some clinical laboratory procedures as statutory exclusions. CMS has clarified that the exclusion only applies when a procedure is performed in the asymptomatic person. "*If a person is tested to rule out or to confirm a suspected diagnosis because the patient has a sign and/or symptoms, this is considered a diagnostic test, not a screening test*."[x] This applies even if the CPT code descriptor includes the term 'screen'. [x,xi]

EXAMPLE: Cytogenomic Constitutional Microarray: The microarray would be considered a screening test from the clinical lab perspective that is performed in a person who has signs or symptoms of an illness. As such, it is not a statutory exclusion. A common use is in the person who has evidence of developmental delay and/or autistic spectrum and additional diagnostic testing is indicated.

Other tests use the same approach. The MolDX Program covers the Tissue of Origin, MammaPrint and Oncotype DX tests which also use the microassay approach.

Based on these points, we believe it has been inaccurately stated that there is no benefit category for some of the molecular pathology procedures. We also believe that the molecular the procedures/services listed as non-covered have been inappropriately designated as 'statutory exclusions'. We believe they are 'reasonable and necessary' decisions that should be presented as Draft LCDs and proceed through the LCD process.

II. Clinical concerns

In our review of the non-covered tests, we have clinical concerns about the thoroughness of the assessment of the medical use of these tests. In some cases, Palmetto is addressing these tests as if they are only used in the asymptomatic person. As a consequence, Palmetto is inappropriately denying the beneficiary access to medically-indicated diagnostic testing.

We believe the LCD process is essential to address these concerns and bring in the experience of the medical community and patient groups. We are concerned that it has been assumed that there are no adult presentations or indications for testing associated with symptoms that require diagnosis and treatment in the adult, including those younger beneficiaries on Medicare because of disability status. Examples of conditions that may have presented earlier in life but not been appropriately diagnosed and managed until later: Marfan's syndrome. Examples of conditions with adult presentation of milder forms or undiagnosed conditions: AAT Deficiency, Cystic Fibrosis and Wilson Disease). An example of a condition with onset later life is Fragile X Tremor and Ataxia (FXTAS). Another concern is related to age by itself or presentation of a condition in different ages as a reason for exclusion from coverage. The discussion of testing and collagen crosslinks by CMS would challenge that decision.[xii] Options must be available that allow for coverage of these conditions at a minimum either through an LCD with clinical criteria defined if volume warrants or through documentation on individual review if the frequency is low enough in all Medicare beneficiaries, including those eligible by disability status.

We would point out that in other webpage statements; the decision to not cover a test is related to the use of the test in diagnosing or treating a condition. Some of the reasons for denial relate to the use of alternative diagnostic methods; this should be presented to the medical community with the evidence used to arrive at that decision to allow input on medical evidence and standard of practice. Another reason for denial is use of the test to confirm a diagnosis. We believe using a diagnostic test to confirm a diagnosis is recognized medical practice, one that is shared by patients and not restricted by the statute, which states only refers to 'diagnosis or treatment'. All 'health-related outcomes' as described by the SACGHS should be accepted reasons related to use of a test.[xiii] They include impact on diagnostic thinking or factors relevant to the patient, e.g. ending the diagnostic odyssey, knowledge of prognosis/disease course for life planning as well as decisions about treatment, long-term planning, psychological impact of having a diagnosis, therapeutic choices relating to the patient's choices as well as the medical choices as well as the patient's choice, and patient outcome which includes mortality, morbidity, change in response to therapy, adverse events, health-related quality of life, pregnancy termination decisions and prenatal interventions.

SUMMARY:

1. We understand the need to identify use of the tests that is not covered by Medicare, specifically the use in asymptomatic persons. However, we do not believe the only way to achieve this is by declaring use of a test for any reason is screening exclusion. In the Negotiated Rulemaking, CMS has demonstrated how it addresses clinical lab procedures used in the asymptomatic patient and the diagnostic use of clinical lab procedures using ICD-9 codes to differentiate their use.

   We support the use of a system as described by CMS. The ICD-9 codes relating to screening would be included in the list of "ICD-9 codes denied". They would identify use in the asymptomatic person which is not covered by Medicare and will be denied as a statutory exclusion. There are ICD-9 codes that address genetic screening for carrier status:

V82.7 Screening for genetic disease carrier status
V83.89 Other genetic carrier status

This approach allows the provider, physician and beneficiary to understand whether the test/procedure will be covered and the reason for the denial. Waiver of liability can be appropriately addressed. This facilitates appropriate claims submission and adjudication. Equally important, this approach allows for the same test to be covered for diagnostic and treatment purposes using a separate list of ICD-9 codes that are covered.

We would suggest that Palmetto

- Develop an Article which is entered into the MCD that addresses the limited definition of 'screening' as a procedure performed for the asymptomatic beneficiary and the statutory exclusion. As an Article addressing statutory exclusion, this could be posted and entered into the MCD. As an Article, it would not be required to go out for public comment although CMS does suggest that the MAC use its discretion and it could be reviewed/commented upon prior to its release.

- Identify in the Article the ICD-9 codes for screening that should be used to indicate that the beneficiary is asymptomatic and that it would be considered 'screening' by Medicare and be a statutory exclusion. These could be identified by using the ICD-9 codes for screening (testing done in the asymptomatic beneficiary), e.g. V82.7 Screening for genetic disease carrier status and V83.89 Other genetic carrier status.

- Suggest they obtain an ABN using the appropriate modifiers for a statutory exclusion.

2. We would request that <u>all</u> tests that have been (and might be in the future) declared non-covered for any indication be presented as LCDs so that the medical community and public can review the evidence used to arrive at this determination and present evidence to support coverage as diagnostic tests. This would include review of the condition and ICD-9 codes that would describe the situations in which the test would be considered to be medically reasonable and necessary. It could also address situations which might generally not meet reasonable and necessary criteria but for which there are limited exceptions where additional documentation could support a determination of medical necessity in certain circumstances.

3. For all statements on the non-covered list (and PTCH1), we would request that Palmetto
   a) Retract all MolDX Program webpage statements.
   b) Publish an Article to address non-coverage for statutory exclusion of testing in asymptomatic patients as defined in CLM 104. Chapter 16. Laboratory Services §120.1. (See #1)
   c) Publish a revised LCD that removes the non-covered status of the molecular pathology codes, removes the requirement that physicians and laboratories use the developer's indications for tests, and removes listing tests as covered if they do not have a primary LCD associated with the coverage decision.
   d) Remove statutory exclusion status from all molecular pathology CPT codes.
      i. Allow for coverage of the Tier 1 and Tier 2 codes.
      ii. Select the high volume or high cost tests to address with an LCD.

e) Remove all automatic edits including frequency edits that are not consistent with the published LCDs.
f) Instruct providers how to resubmit claims that have been inappropriately adjudicated/denied so that they do not receive denials, e.g. for 'duplicate claims'.

---

[i] The total number of posted "Non-Covered Tests" as of 10/16/2013 is 47. However, there have been 49 local decisions for tests that are 'non-covered'. The statement about PTCH1 is incorrectly included on the list of "Covered Tests". The web page for OncoCee was posted on 08/07/2012 and was still on the site on 07/08/2013. However, it was not on the website as of 09/1/2013. Finally, three items on the 'Non-Covered" list are considered 'quality control' or another reason for denial.

[ii] "Negotiated Rulemaking: Coverage and Administrative Policies for Clinical Diagnostic Laboratory Services. Proposed Rule." 65 Federal Register 48 (March 10, 2000), p. 13086.

[iii] "Negotiated Rulemaking: Coverage and Administrative Policies for Clinical Diagnostic Laboratory Services. Final Rule," November 23, 2001. 66 Federal Register 226.(November 23, 2001), pp. 58788-58890.

[iv] Ibid. p. 58788.

[v] *Benefit Policy Manual. Chapter 15. Covered Medical and Other Health Services. §80.1 Clinical Laboratory Services*

[vi] *CLM 104 Chapter 16 §90.1,*

[vii] Negotiated Rulemaking, 66 FR, p. 58793.

[viii] Ibid., p. 58795.

[ix] Ibid., p. 58813.

[x] CLM 104. Chapter 16. Laboratory Services §120.1 Negotiated Rulemaking Implementation. Clarification of the Use of the Term "Screening" or "Screen"

[xi] "Negotiated Rulemaking: Coverage and Administrative Policies for Clinical Diagnostic Laboratory Services. Proposed Rule." 65 Federal Register 48 (March 10, 2000), p. 13087.

[xii] "Negotiated Rulemaking" 66 FR. Discussion of collagen crosslinking, 58797-58799; Coverage of collagen crosslinking pp. 58843-58846.

[xiii] DHHS. U.S. System of Oversight of Genetic Testing: A Response to the Charge of the Secretary of Health and Human Services: Report of the Secretary's Advisory Committee on Genetics, Health, and Society. April 2008. Accessed as http://oba.od.nih.gov/oba/SACGHS/reprots/SACGHS_oversight_report.pdf Last accessed 07.21.2013

NOTE: Should you have landed here as a result of a search engine (or other) link, be advised that these files contain material that is copyrighted by the American Medical Association. You are forbidden to download the files unless you read, agree to, and abide by the provisions of the copyright statement. **Read the copyright statement now and you will be linked back to here.**

NOTE: According to the document properties, this was created by Palmetto on 05/09/2013. We can provide the original copy. It was accessed and saved on 05/26/2013.

MoPath Claims Submission Guidelines

- J11 Part B: Effective for claims processed on and after July 1, 2013
- J1 Part B: Effective for claims processed on and after January 1, 2013

Because the MoPath Tier 2 CPT code descriptions do NOT identify the specific genes tested, laboratory providers that have not obtained a unique 5-digit ID through Palmetto GBA or McKesson Dex must provide additional information until an ID is obtained. As per the MolDx Program, claims submitted in J1 without a unique ID will be denied. Claims submitted in all other areas administered through Palmetto GBA should reference the "Required Text," Column 3, to submit the information required for claim reimbursement.

Column 3 "Required Text" lists key components needed to adjudicate the claim. The first capitalized text in this column represents the acronym for the gene. The acronym is separated by a comma and the following text identifies the components evaluated on the gene including but not limited to the following items: a specific variant, known familial variant, duplication/deletions, exons, and full gene sequence. The table following the MoPath Fee Schedule provides a comprehensive abbreviation key for the test components.

To bill a MoPath service, laboratory providers must enter the appropriate acronym AND the information following the comma in Loop 2400, NTE02, or SV101-7 for the 5010A1 837P or Box 19 for a paper claim adjacent to **each** CPT code used to report the test service.

Example: a lab performs a test for the F1388del variant on the ABCC8 gene. This test would be reported with the following claim components:

- CPT code 81400
- Required text in the SV101-7 field adjacent to the CPT code: ABCC8, F1388del variant

Claims submitted without the required descriptor information or an assigned test ID will be rejected as an invalid submission.

Column 5 "Covered" key

Indicator	Description
Y	Payable Medicare service
SE	Not covered - statutorily excluded from Medicare benefit
N	Not covered –failed reasonable/necessary Medicare criteria
L	Limited coverage per published LCD

CPT codes	CPT Descriptor	Required Text	PGBA-LDT ONLY	Covered	Comment
81161	DMD Dup/Delet Analysis DMD	DMD, dup_del	NO DATA	SE	
81200	ASPA gene	ASPA, cv	$93.90	SE	
81201	APC(adaenomatous polyposis coli full gene sequence	APC, fgs	$749.92	SE	Coverage chge
81202	known familial variants	APC, kfv	$93.94	SE	Coverage chge
81203	duplication/deletion	APC, dup_del	$570.05	SE	Coverage chge
81205	BCKDHB gene	BCKDHB, cv	$123.36	SE	
81206	BCR/ABL1 gene major bp	BCR_ABL1, majbp qual quant	$108.37	Y	
81207	BCR/ABL1 gene minor bp	BCR_ABL1, minbp qual quant	$90.31	Y	
81208	BCR/ABL1 gene other bp	BCR_ABL1, other bp qual quant	$150.17	Y	
81209	BLM gene	BLM, 2281del6ins7	$93.90	SE	
81210	BRAF gene	BRAF, V600E	$97.45	Y	
81211	BRCA1 & 2 seq and com dup/del	BRCA1, BRCA2, fgs cdup_del	$2,795.09	Y	
81212	BRCA1 & 2 185&58385&6174 var	BRCA1, BRCA2, 185delAG, 5385insC, 6174delT	$178.04	Y	
81213	BRCA1 & 2 uncom dup/del var	BRCA1, BRCA2, uncom dup_del	$587.12	Y	
81214	BRCA1 full seq & com dup/del	BRCA1, fgs cdup_del	$1,449.01	Y	
81215	BRCA1 full gene known fam variant	BRCA1, fgs, kfv	$93.94	Y	
81216	BRCA2 gene full sequence	BRCA2, fgs	$1,747.04	SE	
81217	BRCA2 gene known fam variant	BRCA2, kfv	$93.94	Y	
81220	CFTR gene com variants	CFTR, cv	$800.46	SE	
81221	CFTR gene known fam variants	CFTR, kfv	$93.94	SE	
81222	CFTR gene dup/delet variants	CFTR, dup_del	$129.55	SE	
81223	CFTR gene full sequence	CFTR, fgs	$1,554.46	SE	
81224	CFTR gene intron poly t	CFTR, intron 8 poly-T	$82.58	SE	
81225	Cyp2c19 gene com variants	CYP2C19, cv	$319.12	Y	
81226	Cyp2d6 gene com variants	CYP2D6, cv	$426.43	Y	
81227	Cyp2c9 gene com variants	CYP2C9, cv	$169.50	Y	

81228	Cytogen micrarray copy nmbr	Cytogen microarray copy nmbr	$646.14	SE	
81229	Cytogen m array copy no&snp	Cytogen microarray copy nmbr and SNP	$675.56	SE	
81235	EGFR (epidermal growth receptor)(non-small cell lung) gene analyisis, common variants (eg exon 19 LREA deletion, L858R, T790M, G719A, G719S, L861Q)	EGFR, cv	$225.00	Y	
81240	F2 gene	F2, 20210G>A	$41.41	Y	
81241	F5 gene	F5, Leiden	$78.39	Y	
81242	FANCC gene	FANCC, cv	$93.90	SE	
81243	FMR1 gene detection	FMR1	$60.51	SE	
81244	FMR1 gene characterization	FMR1, ma	$100.09	SE	
81245	FLT3 gene	FLT3, dup	$112.00	Y	
81250	G6PC gene	G6PC, cv	$93.90	SE	
81251	GBA gene	GBA, cv	$93.90	SE	
81252	GJB2 (gap junction protein, common variants	GJB2, fgs	$156.64	SE	
81253	known familial variants	GJB2, kfv	$81.56	SE	
81254	GJB6 gap junction protein gene analyisis, common variants	GJB6, cv	$74.97	SE	
81255	HEXA gene	HEXA, cv	$93.90	SE	
81256	HFE gene	HFE, cv	$70.20	Y	
81257	HBA1/HBA2gene	HBA1_HBA2, cdel or v	$183.22	SE	Coverage chge
81260	IKBKAP gene	IKBKAP, cv	$93.90	SE	
81261	IGH gene rearrange amp meth	IGH, amp	$148.12	Y	
81262	IGH gene rraange dir probe	IGH, dp	$51.12	Y	
81263	IGH vari regional mutation	IGH, variable region	$259.93	Y	
81264	IGH rearrangebn clonal pop	lGK, gr	$111.98	Y	
81265	Str markers specimen anal	STR	$414.94	Y	
81266	Str markers and addl	STR add	NO DATA	N	
81267	Chimerism anal no cell selec	Chimerism	$149.72	Y	
81268	Chimerism anal w/cell selec	Chimerism, add cell	$149.72	Y	
81270	JAK2 gene	JAK2, V617F	$82.88	Y	
81275	KRAS gene	KRAS, codons 12 and 13	$246.40	Y	
81280	Long qt synd gene full sequence (12 genes)	LQT, fgs 12 genes	NO DATA	SE	
81281	Long qt synd known fam var	LQT, kfv	NO DATA	SE	

81282	Long qt syn gene dup/dlt var (12 genes)	LQT, dup_del 12 genes	NO DATA	SE	
81290	MCOLN1 gene	MCOLN1, cv	$93.90	SE	
81291	MTHFR gene	MTHFR, cv	$92.92	Y	
81292	MLH1 gene full seq	MLH1, fgs	$803.28	Y	
81293	MLH1 gene known variants	MLH1, kfv	$93.94	Y	
81294	MLH1 gene dup/delete variant	MLH1, dup_del	$491.96	Y	
81295	MSH2 gene full seq	MSH2, fgs	$787.22	Y	
81296	MSH2, gene known variants	MSH2, kfv	$93.94	Y	
81297	MSH2, gene dup/delete variants	MSH2, dup_del	$542.77	Y	
81298	MSH6 gene full seq	MSH6, fgs	$617.61	Y	
81299	MSH6 gene known variants	MSH6, kfv	$93.94	Y	
81300	MSH6 gene dup/delete variants	MSH6, dup_del	$505.15	Y	
81301	Microsatellite instability	MSI	$320.84	Y	
81302	MECP2 gene full seq(Rhetts)	MECP2, fgs	$312.94	SE	
81303	MECP2gene known variant(Rhetts)	MECP2, kfv	$117.68	SE	
81304	MECP2 gene dup/delete variants (Rhetts)	MECP2, dup_del	$85.42	SE	
81310	NPM1 gene	NPM1, exon 12	$58.84	Y	
81315	PML/RAR alpha com breakpoints	PML_RAR, cbp quant qual	$117.54	Y	
81316	PML/RAR alpha com 1 breakpoint	PML_RAR, sbp quant qual	NO DATA	Y	
81317	PMS2 gene full seq analysis	PMS2, fgs	$642.58	Y	
81318	PMS2 known familial variants	PMS2, kfv	$93.94	Y	
81319	PMS2 gene dup/delete variants	PMS2, dup_del	$462.42	Y	
81321	PTEN gene analyis, full sequence	PTEN, fgs	$605.24	Y	
81322	known familial variants	PTEN, kfv	$58.84	Y	
81323	duplication/deletion	PTEN, dup_del	$88.26	Y	
81324	PMP22 gene analysis, duplication/deletion	PMP22, dup_del	$486.16	SE	
81325	full sequence analysis	PMP22, fgs	$297.24	SE	
81326	known familial variants	PMP22, kfv	$93.94	SE	Coverage Change
81330	SMPD1 gene common variants	SMPD1, cv	$93.90	SE	
81331	SNRPN/UBE3A gene	SNRPN_UBE3A, ma	$73.22	SE	
81332	SERPINA1 gene	SERPINA, cv	$70.20	Y	
81340	TRB @gene rearrange amplify	TRB, beta amp	$148.12	Y	
81341	TRB @gene rearrange	TRB, dp	$45.44	Y	

	dirporbe				
81342	TRG gene rearrangement anal	TRG, gamma	$148.12	Y	
81350	UGT1A1 gene	UGT1A1, cv	$67.25	SE	
81355	VKORC1 gene	VKORC1, cv	$83.19	Y	
81370	HLA I & II typng lr	HLA I-II, lr	$552.75	Y	
81371	HLA I & II type verify lr	HLA I-II, lr A, B, DRB	$330.84	Y	
81372	HLA I typing complete lr	HLA I, lr complete	$303.64	Y	
81373	HLA I typing 1 locus lr	HLA I lr locus ea	$153.08	Y	
81374	HLA I typing 1 antigen lr	HLA I, lr antigen ea	$100.00	Y	
81375	HLA II typing ag equiv lr	HLA II, lr DRB1, DQB1	$303.43	Y	
81376	HLA II typing 1 locus lr	HLA II, lr locus ea	$168.00	Y	
81377	HLA II type 1 ag equiv lr	HLA II, lr antigen ea	$126.20	Y	
81378	HLA I & II typing hr	HLA I-II, hr	$475.00	Y	
81379	HLA I typing complete hr	HLA I, hr complete	$461.00	Y	
81380	HLA I typing 1 locus hr	HLA I, hr locus ea	$243.64	Y	
81381	HLA I typing 1 allele hr	HLA I, hr allele ea	$130.00	Y	
81382	HLA II typing 1 loc hr	HLA II, hr locus ea	$170.00	Y	
81383	HLA II typing 1 allele hr	HLA II, hr allele ea	$150.00	Y	
81400	**Tier 2**	**Mopath procedure level 1**			
81400	ABCC8	ABCC8, F1388del	NO DATA	SE	
81400	ACADM	ACADM, K304E	$99.62	SE	
81400	ACE	ACE, idv	$82.58	Y	
81400	AGTR1	AGTR1, 1166A>C	$75.88	SE	
81400	CCR5	CCR5, del	$75.88	SE	
81400	CLRN1	CLRN1, N48K	$93.94	SE	
81400	DPYD	DPYD, IVS14+1G>A	$81.70	SE	
81400	DYT1 (TOR1A)	DYT1(TOR1A), IVS14+1G>A	$106.32	SE	
81400	F2	F2, 1199G>A	$70.20	Y	
81400	F5	F5, HR2	$82.58	Y	
81400	F7	F7, R353Q	$64.52	Y	
81400	F13B	F13B, V34L	$64.52	Y	
81400	FGB	FGB, -455G>A	$70.20	Y	
81400	FGFR3	FGFR3, P250R	$52.14	SE	
81400	Human Platelet Antigen ANTIGEN 1(HPA-1)	HPA, antigen ea	$46.46	Y	
81400	Human Platelet Antigen ANTIGEN 2(HPA-2)	HPA, antigen ea	$46.46	Y	
81400	Human Platelet Antigen ANTIGEN 3(HPA-3)	HPA, antigen ea	$46.46	Y	

81400	Human Platelet Antigen ANTIGEN 4(HPA-4)	HPA, antigen ea	$46.46	Y	
81400	Human Platelet Antigen ANTIGEN 5(HPA-5)	HPA, antigen ea.	$46.46	Y	
81400	Human Platelet Antigen ANTIGEN 6(HPA-6)	HPA, antigen ea	$46.46	Y	
81400	Human Platelet Antigen ANTIGEN 9(HPA-9)	HPA, antigen ea	$46.46	Y	
81400	Human Platelet Antigen ANTIGEN 15 (HPA-15)	HPA, antigen ea	$46.46	Y	
81400	IVD	IVD, A282V	$46.46	SE	
81400	SERPINE1	SERPINE1, 4G	$58.84	Y	
81400	SHOC2-NOONAN-LIKE SYNDROME	SHOC2, S2G	NO DATA	SE	
81400	SMN1	SMN1, exon 7 del	$70.20	SE	
81400	SRY	SRY	NO DATA	SE	
81401	**Tier 2**	**Mopath procedure level 2**			
81401	ABL1 (c-abl oncogene 1	ABL1, T315I	$153.01	Y	
81401	ACADM (acyl-CoA dehydrogenase	ACADM, cv	NO DATA	SE	
81401	ADRB2	ADRB2, cv	$55.49	SE	
81401	APOB	APOB, cv	NO DATA	SE	
81401	APOE	APOE, cv	$46.46	SE	
81401	AR (androgen receptor	AR, alleles	NO DATA	SE	
81401	ATN1	ATN1	$58.84	SE	
81401	CBFB/MYH11	CBFB_MYH11, quan qual	NO DATA	SE	
81401	CBS	CBS, cv	NO DATA	SE	
81401	CCND1/IGH	CCND1_IGH, ta majbp qual qual	$93.94	Y	
81401	CFH/ARMS2	CFH_ARMS2, cv	$90.59	SE	
81401	CYP3A4	CYP3A4, cv	$46.46	SE	
81401	CYP3A5	CYP3A5, cv	$46.46	SE	
81401	CYFB-MYH11	CYFB_MYH11, cv	$138.82	Y	
81401	DMPK (dystrophia myotonica-protein kinase	DMPK	$66.41	SE	
81401	E2A/PBX1	E2A_PBX1, ta qual quan,	$105.30	Y	
81401	EML4-ALK	EML4_ALK, ta or ia	$128.48	Y	

81401	ETV6-RUNX1	ETV6_RUNX1, ta qual quan	$90.31	Y	
81401	EWSR1/ERG	EWSR1_ERG, ta qual quan	$151.42	Y	
81401	EWSR1/FLI1	EWSR1_FLI1, ta qual quan	$162.85	Y	
81401	EWSR1/WT1	EWSR1_WT1, ta qual quan	$203.84	Y	
81401	F11coagulation factor XI	F11, cv	$75.88	Y	
81401	FGFR3	FGFR3, cv	$84.91	SE	
81401	FIP1L1-PDGFR	FIP1L1_PDGFR, qual quan	$90.82	Y	
81401	FOXO1/PAX3	FOXO1_PAX3, ta, qual quan	$120.75	Y	
81401	FOXO1/PAX7	FOXO1_PAX7, ta, qual quan	$120.75	Y	
81401	FXN (frataxin	FXN, alleles	NO DATA	SE	
81401	GALT (galactose-1-phosphate uridylyltransferase	GALT, cv	$299.08	SE	
81401	H19	H19, ma	$112.00	SE	
81401	HBB (hemoglobin, beta	HBB, cv	$147.81	Y	
81401	HTT (huntingtin	HTT, alleles	$82.58	SE	
81401	KCNQ10T1 (KCNQ1 overlapping transcript 1	KCNQ10T1 , ma	NO DATA	SE	
81401	MEG3/DLK1	MEG3_DLK1, ma	NO DATA	SE	
81401	MLL/AFF	MLL_AFF1, ta qual quan	$101.67	SE	
81401	MLL/MLLT3	MLL_MLLT3, ta, qual quan	NO DATA	SE	
81401	MT-ATP6	MT-ATP6, cv	NO DATA	SE	
81401	MT-ND4, MT-ND6	MT-ND4, MT-ND6, cv	$131.08	SE	
81401	MT-ND5 mitochondrially encoded tRNA leucine 1 [UUA/G] mitochondrially encoded NADH dehydrogenase 5)	MT-ND5, cv	$183.22	SE	
81401	MT-RNR1 (mitochondrially encoded 12S RNA)	MT-RNR1, cv	$85.93	SE	
81401	MT-TK (mitochondrially encoded tRNA lysine)	MT-TK, cv	NO DATA	SE	

81401	MT-TL1	MT-TL1, cv	NO DATA	SE	
81401	MT-TS1	MT-TS1, cv	$130.38	SE	
81401	MUTYH (mutY homolog [E.coli])	MUTYH, cv	$82.07	Y	
81401	NPM/ALK	NPM_ALK, ta	NO DATA	Y	Coverage Change
81401	PAX8/PPARG	PAX8_PPARG, ta	$54.19	Y	
81401	PRSS1 (protease, serine, 1 [trypsin 1])	PRSS1, cv	$105.30	SE	
81401	PYGM	PYGM, cv	NO DATA	SE	
81401	RUNX1/RUNX1T1	RUNX1_RUNX1T1, ta qual quan	$106.05	Y	
81401	SEPT9 (Septin 9)	SEPT9, ma	$90.59	SE	
81401	SMN1/SMN2 (survival of motor neuron 1, telomeric/survival of motor neuron 2, centromeric	SMN1_SMN2, dosage	$74.75	SE	
81401	TPMT (thiopurine S-methyltransferase)	TPMT, cv	$111.61	Y	
81401	TYMS (thymidylate synthetase)	TYMS, trv	$169.10	Y	
81401	VWF (von Willebrand factor	VWF, cv	$278.18	Y	
81402	**Mopath procedure level 3**				
81402	CYP21A2	CYP21A2 , cv	$390.18	SE	
81402	Chromosome 18q-	C18q	NO DATA	SE	
81402	ESR1/PGR	ESR1_PGR, ratio	NO DATA	SE	
81402		IGH_BCL2, majbpr and mcr bp qual quan	NO DATA	Y	
81402	KIT	KIT, cv	$98.13	Y	
81402	MEFV (Mediterranean fever) (eg, familial Mediterranean fever),	MEFV, cv	$138.58	SE	
81402	MPL	MPL, cv	$101.45	Y	
81402	TRD	TRD, gr	NO DATA	SE	
81402	Uniparental disomy (UPD)	UPD, str	$130.05	SE	
81403	**Mopath procedure level 4**				
81403	ABL1 (c-abl oncogene 1	ABL1	$156.89	Y	
81403	ANG (angiogenin, ribonuclease, RNase A family,	ANG, fgs	NO DATA	SE	

	5				
81403	CEBPA	CEBPA, fgs	$235.54	Y	
81403	CEL (carboxyl ester lipase [bile salt-stimulated lipase	CEL, exon 11	NO DATA	SE	
81403	DAZ/SRY	DAZ_SRY, cdel	NO DATA	SE	
81403	F8 (coagulation factor VIII	F8, intron 1 and 22a	$81.05	Y	
81403	FGFR3 (fibroblast growth factor receptor 3	FGFR3, exon 7	$88.26	SE	
81403	GJB1 (gap junction protein, beta 1) (eg, Charcot-Marie-Tooth X-linked), full gene sequence	GJB1, fgs	NO DATA	SE	
81403	HBB (hemoglobin, beta, beta-globin beta thalassemia	HBB, dup_del	NO DATA	SE	
81403	HRAS (v-Ha-ras Harvey rat sarcoma viral oncogene homolog Costello syndrome	HRAS, exon 2	$88.33	SE	
81403	IDH1	IDH1, exon 4	$67.70	Y	
81403	IDH2 (isocitrate dehydrogenase 2	IDH2, exon 4	$67.70	Y	
81403	JAK2 (Janus kinase 2	JAK2, exon 12 and 13	$109.14	Y	
81403	KRAS (v-Ki-ras2 Kirsten rat sarcoma viral oncogene)	KRAS, exon 3	NO DATA	SE	
81403	MPL (myeloproliferative leukemia virus oncogene, thrombopoietin receptor, TPOR	MPL , exon 10	$106.32	Y	
81403	MT-RNR1 (mitochondrially encoded 12S RNA	MT-RNR1, fgs	$114.72	SE	
81403	MT-TS1 (mitochondrially encoded tRNA serine 1	MT-TS1 , fgs	$114.72	SE	
81403	SMN1 (survival of motor neuron 1, telomeric)	SMN1, kfv	NO DATA	SE	
81403	VHL (von Hippel-Lindau tumor suppressor	VHL , dup_del	$83.60	Y	
81403	VWF (von Willebrand factor	VWF, tsa	$284.20	Y	
81404	**Mopath procedure level 5**				
81404	ACADS (acyl-CoA dehydrogenase	ACADS, tsa	$247.74	SE	
81404	AQP2 (aquaporin 2 [collecting duct])	AQP2, fgs	NO DATA	SE	
81404	ARX (aristaless related homeobox) (	ARX, fgs	NO DATA	SE	
81404	BTD (biotinidase	BTD, fgs	$328.05	SE	

81404	CAV3 (caveolin 3) (eg, CAV3-related distal myopathy, limb-girdle muscular dystrophy type 1C), full gene sequence	CAV3, fgs	NO DATA	SE	
81404	CDKN2A (cyclin-dependent kinase inhibitor 2A	CDKN2A, fgs	$373.14	Y	
81404	CLRN1 (clarin 1) (	CLRN1, fgs	NO DATA	SE	
81404	CPT2 (carnitine palmitoyltransferase	CPT2, fgs	NO DATA	SE	
81404	CYP1B1 (cytochrome P450, family 1, subfamily B, polypeptide 1)	CYP1B1 , fgs	$278.18	SE	
81404	DMPK (dystrophia myotonica-protein kinase	DMPK	$66.41	SE	
81404	EGR2 (early growth response 2) (eg, Charcot-Marie-Tooth	EGR2, fgs	$296.24	SE	
81404	FGFR2 (fibroblast growth factor receptor 2)	FGFR2, exons 8,10	$368.90	SE	
81404	FGFR3 (fibroblast growth factor receptor 3) (	FGFR3, exons 8,11,12,13	$280.51	SE	
81404	FKRP (Fukutin related protein)	FKRP, fgs	NO DATA	SE	
81404	FOXG1 (forkhead box G1)	FOXG1 , fgs	$325.66	SE	
81404	FSHMD1A (facioscapulohumeral muscular dystrophy 1A)	FSHMD1A	NO DATA	SE	
81404	FXN (frataxin)	FXN, fgs	NO DATA	SE	
81404	HBA1/HBA2 (alpha globin 1 and alpha globin 2)	HBA1_HBA2, dup_del	NO DATA	SE	
81404	HBB (hemoglobin, beta, beta-globin) (	HBB, fgs	$206.96	SE	
81404	HNF1B (HNF1 homeobox B) (eg, maturity-onset diabetes of the	HNF1B, dup_del	NO DATA	SE	
81404	HRAS (v-Ha-ras Harvey rat sarcoma viral oncogene homolog)	HRAS, fgs	NO DATA	SE	
81404	KCNJ10 (potassium inwardly-rectifying channel, subfamily J, member 10	KCNJ10, fgs	NO DATA	SE	
81404	KIT (C-kit) (v-kit Hardy-Zuckerman 4 feline sarcoma	KIT, tga	$213.47	Y	

81404	LITAF (lipopolysaccharide-induced TNF factor)	LITAF, fgs	NO DATA	SE	
81404	MEFV (Mediterranean fever	MEFV, fgs	$329.41	SE	Coverage Change
81404	MEN1 (multiple endocrine neoplasia I	MEN1, dup_del	NO DATA	SE	
81404	NRAS (neuroblastoma RAS viral oncogene homolog)	NRAS, exon 1, 2	$148.04	Y	
81404	PDGFRA (platelet-derived growth factor receptor alpha polypeptide) (e	PDGFRA, exons 12,18	$111.44	Y	
81404	PDX1 (pancreatic and duodenal homeobox	PDX1, fgs	NO DATA	SE	
81404	PRNP (prion protein	PRNP, fgs	NO DATA	SE	
81404	PRSS1 (protease, serine, 1 [trypsin 1])	PRSS1, fgs	$248.76	Y	
81404	RAF1 (v-raf-murine leukemia viral oncogene homolog 1)	RAF1, exons 7, 12,14,17	NO DATA	SE	
81404	RET (RET proto-oncogene)	RET, cv	NO DATA	SE	
81404	SDHD (succinate dehydrogenase complex, subunit D, integral membrane protein	SDHD, fgs	NO DATA	SE	
81404	SLC25A4 (solute carrier family 25 [mitochondrial carrier; adenine nucleotide translocation],	SLC25A4, fgs	NO DATA	SE	
81404	TP53 (tumor protein 53	TP53, 2-5 exons	NO DATA	SE	
81404	TTR (transthyretin	TTR, fgs	NO DATA	SE	
81404	TYR (tyrosinase [oculocutaneous albinism IA])	TYR, fgs	NO DATA	SE	
81404	USH1G (Usher syndrome 1G [autosomal recessive])	USH1G, fgs	NO DATA	SE	
81404	VHL (von Hippel-Lindau tumor suppressor)	VHL, fgs	$639.96	Y	
81404	VWF (von Willebrand factor)	VWF, tsa	NO DATA	SE	
81405	**Mopath procedure level 6**				
81405	ABCD1 (ATP-binding cassette, sub-family D [ALD],	ABCD1, fgs	NO DATA	SE	
81405	ACADS (acyl-CoA	ACADS, fgs	NO	SE	

	dehydrogenase, C-2 to C-3 short chain) (eg, short chain acyl-CoA		DATA		
81405	ACTC1 (actin, alpha, cardiac muscle 1) (eg	ACTC1, fgs	NO DATA	SE	
81405	APTX (aprataxin	APTX, fgs	NO DATA	SE	
81405	AR (androgen receptor	AR, fgs	NO DATA	SE	
81405	CHRNA4 (cholinergic receptor, nicotinic, alpha 4) (	CHRNA4 , fgs	NO DATA	SE	
81405	CHRNB2 (cholinergic receptor, nicotinic, beta 2 [neuronal	CHRNB2, fgs	NO DATA	SE	
81405	CYP21A2 (cytochrome P450, family 21, subfamily A, polypeptide2	CYP21A2, fgs	$147.10	SE	
81405	DFNB59 (deafness, autosomal recessive 59)	DFNB59, fgs	NO DATA	SE	
81405	DHCR7 (7-dehydrocholesterol reductase	DHCR7, fgs	NO DATA	SE	
81405	EYA1 (eyes absent homolog 1 [Drosophila])	EYA1, dup_del	NO DATA	SE	
81405	F9 (coagulation factor IX)	F9, fgs	NO DATA	SE	
81405	FH (fumarate hydratase	FH, fgs	NO DATA	SE	
81405	FKTN (fukutin) (eg, limb-girdle muscular dystrophy	FKTN, fgs	NO DATA	SE	
81405	GFAP (glial fibrillary acidic protein)	GFAP, fgs	NO DATA	SE	
81405	GLA (galactosidase, alpha	GLA, fgs	NO DATA	SE	
81405	HBA1/HBA2 (alpha globin 1 and alpha globin 2	HBA1_HBA2, fgs	NO DATA	SE	
81405	HNF1A (HNF1 homeobox A	HNF1A, fgs	NO DATA	SE	
81405	HNF1B (HNF1 homeobox B)	HNF1B, fgs	NO DATA	SE	
81405	KRAS (v-Ki-ras2 Kirsten rat sarcoma viral oncogene homolog)	KRAS, fgs	NO DATA	SE	
81405	LAMP2 (lysosomal-associated membrane protein 2) (	LAMP2, fgs	NO DATA	SE	
81405	MEN1 (multiple endocrine	MEN1, fgs	$426.32	Y	

	neoplasia I				
81405	MPZ (myelin protein zero)	MPZ, fgs	$296.24	SE	
81405	MYL2 (myosin, light chain 2, regulatory, cardiac, slow)	MYL2, fgs	NO DATA	SE	
81405	MYL3 (myosin, light chain 3, alkali, ventricular, skeletal, slow)	MYL3, fgs	NO DATA	SE	
81405	MYOT (myotilin)	MYOT, fgs	NO DATA	SE	
81405	NEFL (neurofilament, light polypeptide) (	NEFL, fgs	NO DATA	SE	
81405	NF2 (neurofibromin 2 [merlin]) (e	NF2, dup_del	NO DATA	SE	
81405	NSD1 (nuclear receptor binding SET domain protein 1)	NSD1, dup_del	NO DATA	SE	
81405	OTC (ornithine carbamoyltransferase)	OTC, fgs	NO DATA	SE	
81405	PDHB (pyruvate dehydrogenase [lipoamide] beta)	PDHB, fgs	NO DATA	SE	
81405	PSEN1 (presenilin 1)	PSEN1, fgs	NO DATA	SE	
81405	RET (RET proto-oncogene) (eg, multiple endocrine neoplasia, type 2A and familial medullary thyroid carcinoma)	RET, tsa	NO DATA	SE	
81405	SDHB (succinate dehydrogenase complex, subunit B, iron sulfur) (eg, hereditary paragangli	SDHB, fgs	NO DATA	SE	
81405	SDHC (succinate dehydrogenase complex, subunit C, integral membrane protein, 15kDa)	SDHC, fgs	NO DATA	SE	
81405	SGCA (sarcoglycan, alpha [50kDa dystrophin-associated glycoprotein]	SGCA, fgs	NO DATA	SE	
81405	SGCB (sarcoglycan, beta [43kDa dystrophin-associated glycoprotein]) (	SGCB, fgs	NO DATA	SE	
81405	SGCD (sarcoglycan, delta [35kDa dystrophin-associated glycoprotein])	SGCD, fgs	NO DATA	SE	

81405	SGCG (sarcoglycan, gamma [35kDa dystrophin-associated glycoprotein])	SGCG, fgs	NO DATA	SE	
81405	SHOC2 (soc-2 suppressor of clear homolog)	SHOC2, fgs	NO DATA	SE	
81405	SMN1 (survival of motor neuron 1, telomeric)	SMN1, fgs	NO DATA	SE	
81405	SPRED1 (sprouty-related, EVH1 domain containing 1)	SPRED1, fgs	NO DATA	SE	
81405	TGFBR1 (transforming growth factor, beta receptor 1) (	TGFBR1, fgs	NO DATA	SE	
81405	TGFBR2 (transforming growth factor, beta receptor 2)	TGFBR2, fgs	NO DATA	SE	
81405	THRB (thyroid hormone receptor, beta)	THRB, fgs >5 exons	NO DATA	SE	
81405	TNNI3 (troponin 1, type 3 [cardiac])	TNNI3, fgs	NO DATA	SE	
81405	TP53 (tumor protein 53) (eg, Li-Fraumeni syndrome, tumor	TP53, fgs or tsa >5 exons	NO DATA	SE	
81405	TPM1 (tropomyosin 1 [alpha])	TPM1, fgs	NO DATA	SE	
81405	TSC1 (tuberous sclerosis 1	TSC1, dup_del	NO DATA	SE	
81405	VWF (von Willebrand factor)	VWF, tsa	$292.63	Y	
81406	**Mopath procedure level 7**				
81406	ACADVL (acyl-CoA dehydrogenase, very long chain) (eg	ACADVL, fgs	NO DATA	SE	
81406	ACTN4 (actinin, alpha 4)	ACTN4, fgs	NO DATA	SE	
81406	ANO5 (anoctamin 5)	ANO5, fgs	$331.85	SE	
81406	APP (amyloid beta [A4] precursor protein) (eg	APP, fgs	NO DATA	SE	
81406	ATP7B (ATPase, Cu++ transporting, beta polypeptide)	ATP7B, fgs	NO DATA	Y	Coverage chg
81406	BRAF (v-raf murine sarcoma viral oncogene homolog B1)	BRAF, fgs	NO DATA	SE	
81406	CAPN3 (Calpain 3)	CAPN3, fgs	$538.98	Y	
81406	CBS (cystathionine-beta-synthase)	CBS, fgs	NO DATA	SE	
81406	CDH1 (cadherin 1, type 1, E-cadherin [epithelial])	CDH1, fgs	NO DATA	SE	
81406	CDKL5 (cyclin-dependent kinase-like 5) (	CDKL5, fgs	$120.88	SE	

81406	DLAT (dihydrolipoamide S-acetyltransferase)	DLAT, fgs	NO DATA	SE	
81406	DLD (dihydrolipoamide dehydrogenase)	DLD, fgs	$561.68	SE	
81406	EYA1 (eyes absent homolog 1 [Drosophila])	EYA1, fgs	$402.56	SE	
81406	F8 (coagulation factor VIII)	F8, dup_del	$1,227.78	SE	
81406	GAA (glucosidase, alpha; acid)	GAA, fgs	NO DATA	SE	
81406	GALT (galactose-1-phosphate uridylyltransferase)	GALT, fgs	$88.26	SE	
81406	GCDH (glutaryl-CoA dehydrogenase)	GCDH, fgs	NO DATA	SE	
81406	GCK (glucokinase [hexokinase 4])	GCK, fgs	$356.96	SE	
81406	HADHA (hydroxyacyl-CoA dehydrogenase/3-ketoacyl-CoA thiolase/enoyl-CoA hydratase [trifunctional protein] alpha subunit)	HADHA, fgs	NO DATA	SE	
81406	HEXA (hexosaminidase A, alpha polypeptide)	HEXA, fgs	NO DATA	SE	
81406	HNF4A (hepatocyte nuclear factor 4, alpha)	HNF4A, fgs	$75.88	SE	
81406	IVD (isovaleryl-CoA dehydrogenase) (eg	IVD, fgs	$533.13	SE	
81406	JAG1 (jagged 1) (	JAG1, dup_del	NO DATA	SE	
81406	LDB3 (LIM domain binding 3) (eg, familial	LDB3, fgs	NO DATA	SE	
81406	LMNA (lamin A/C)	LMNA, fgs	NO DATA	SE	
81406	MAP2K1 (mitogen-activated protein kinase 1)	MAP2K1, fgs	NO DATA	SE	
81406	MAP2K2 (mitogen-activated protein kinase 2) (	MAP2K2, fgs	NO DATA	SE	
81406	MCCC2 (methylcrotonoyl-CoA carboxylase 2 [beta])	MCCC2, fgs	NO DATA	SE	
81406	MUTYH (mutY homolog [E. coli])	MUTYH, fgs	$548.35	SE	
81406	NF2 (neurofibromin 2 [merlin]) (eg	NF2, fgs	NO DATA	SE	
81406	NOTCH3 (notch 3)	NOTCH3, tsa	$367.46	SE	
81406	NSD1 (nuclear receptor binding SET domain protein	NSD1, fgs	$945.81	SE	

	1)				
81406	OPA1 (optic atrophy 1) (eg, optic atrophy),	OPA1, dup_del	NO DATA	SE	
81406	PAH (phenylalanine hydroxylase)	PAH, fgs	NO DATA	SE	
81406	PALB2 (partner and localizer of BRCA2)	PALB2, fgs	$645.64	SE	
81406	PAX2 (paired box 2)	PAX2, fgs	NO DATA	SE	
81406	PC(pyruvate carboxylase	PC, fgs	$252.68	SE	
81406	PCCB (propionyl CoA carboxylase, beta polypeptide	PCCB, fgs	NO DATA	SE	
81406	PDHA1 (pyruvate dehydrogenase [lipoamide] alpha1)	PDHA1, fgs	NO DATA	SE	
81406	PDHX (pyruvate dehydrogenase complex, component	PDHX, fgs	$402.56	SE	
81406	POLG (polymerase [DNA directed], gamma)	POLG, fgs	NO DATA	SE	
81406	POMGNT1 (protein O-linked mannose beta1, 2-N acetylglucosaminyltransferase)	POMGNT1, fgs	NO DATA	SE	
81406	POMT1 (protein-O-mannosyltransferase 1)	POMT1, fgs	NO DATA	SE	
81406	POMT2 (protein-O-mannosyltransferase 2) (	POMT2, fgs	NO DATA	SE	
81406	PRKAG2 (protein kinase, AMP-activated, gamma 2 non-catalytic subunit)	PRKAG2, fgs	NO DATA	SE	
81406	PSEN2 (presenilin 2[Alzheimer's disease 4])	PSEN2, fgs	NO DATA	SE	
81406	PTPN11 (protein tyrosine phosphatase, non-receptor type 11)	PTPN11, fgs	NO DATA	SE	
81406	PYGM (phosphorylase, glycogen, muscle) (	PYGM, fgs	$664.21	N	
81406	RAF1 (v-raf-1 murine leukemia viral oncogene homolog 1)	RAF1, fgs	NO DATA	SE	
81406	RET (ret-proto-oncogene	RET, fgs	$168.83	Y	
81406	RYR1 (ryanodine receptor 1, skeletal)	RYR1, tsa	NO DATA	SE	
81406	SLC26A4 (solute carrier family 26, member 4)	SLC26A4, fgs	NO DATA	SE	

81406	SLC9A6 (solute carrier family 9 [sodium/hydrogen exchanger] member 6)	SLC9A6, fgs	$687.44	SE	
81406	SOS1 (son of sevenless homolog 1) (eg	SOS1, fgs	$990.66	SE	
81406	TAZ (tafazzin)	TAZ, fgs	NO DATA	SE	
81406	TNNT2 (troponin T, type 2 [cardiac])	TNNT2, fgs	NO DATA	SE	
81406	TSC1 (tuberous sclerosis 1)	TSC1, fgs	NO DATA	SE	
81406	TSC2 (tuberous sclerosis 2)	TSC2, dup_del	NO DATA	SE	
81406	UBE3A (ubiquitin protein ligase	UBE3A, fgs	$794.78	SE	
81406	VWF (von Willebrand factor)	VWF, etsa	NO DATA	SE	
81407	**Mopath procedure level 8**				
81407	ABCC8 (ATP-binding cassette, sub-family C [CFTR/MRP], member 8)	ABCC8, fgs	NO DATA	SE	
81407	CHD7 (chromodomain helicase DNA binding protein 7)	CHD7, fgs	NO DATA	SE	
81407	F8 (coagulation factor VIII)	F8, fgs	$1,649.42	SE	
81407	JAG1 (jagged 1)	JAG1, fgs	NO DATA	SE	
81407	MYBPC3 (myosin binding protein C, cardiac)	MYBPC3, fgs	NO DATA	SE	
81407	MYH6 (myosin, heavy chain 6, cardiac muscle, alpha)	MYH6, fgs	NO DATA	SE	
81407	MYH7 (myosin, heavy chain 7, cardiac muscle, beta)	MYH7, fgs	NO DATA	SE	
81407	MYO7A (myosin VIIA)	MYO7A , fgs	NO DATA	SE	
81407	NOTCH1 (notch 1) (	NOTCH1, fgs	NO DATA	SE	
81407	OPA1 (optic atrophy	OPA1, fgs	NO DATA	SE	
81407	PCDH15 (protocadherin-related 15)	PCDH15, fgs	NO DATA	SE	
81407	SCN1A (sodium channel, voltage-gated, type 1, alpha subunit)	SCN1A, fgs	NO DATA	SE	
81407	SCN5A (sodium channel,	SCN5A, fgs	NO	SE	

	voltage-gated, type V, alpha subunit)		DATA		
81407	TSC2 (tuberous sclerosis 2)	TSC2, fgs	NO DATA	SE	
81407	USH1C (Usher syndrome 1C [autosomal recessive, severe])	USH1C, fgs	NO DATA	SE	
81408	**Mopath procedure level 9**				
81408	ATM (ataxia telangiectasia mutated)	ATM , fgs	NO DATA	SE	
81408	CDH23 (cadherin-related 23)	CDH23 , fgs	NO DATA	SE	
81408	COL1A1 (collagen, type I, alpha 1)	COL1A1, fgs	NO DATA	SE	
81408	COL1A2 (collagen, type I, alpha 2)	COL1A2 , fgs	NO DATA	SE	
81408	DYSF (dysferlin, limb girdle muscular dystrophy 2B [autosomal recessive])	DYSF, fgs	NO DATA	SE	
81408	FBN1 (fibrillin 1	FBN1, fgs	NO DATA	SE	
81408	NF1 (neurofibromin 1)	NF1, fgs	NO DATA	SE	
81408	RYR1 (ryanodine receptor 1, skeletal)	RYR1, fgs	NO DATA	SE	
81408	USH2A (Usher syndrome 2A [autosomal recessive, mild])	USH2A, fgs	NO DATA	SE	
81408	VWF (von Willebrand factor) (eg, von Willebrand disease types 1 and 3),	VWF, fgs	NO DATA	SE	

Descriptor column abbreviation key

Abbreviation Key	lower case claim text
Amplified	amp
Additional	add
Breakpoints	bp
Common	c
common duplilcations_deletions	cdup_del
common variants	cv
comon breakpoints	cbp
Deletion	del
direct probe	dp
Duplication	dup

duplication_deletion	dup_del
Each	ea
extended targeted sequence analysis	etsa
full gene sequence	fgs
gene rearrangement	gr
high resolution	hr
insertion/deletion variant	idv
inversion analysis	ia
known familial variants	kfv
low resolution	lr
major breakpoint	majbp
major breakpoint region	mbpr
methylation analysis	ma
Microsatellite instability	MSI
minor breakpoint	minbp
minor cluster region	mcr
Number	nmbr
Qualitative	qual
Quantitative	quan
short tandem repeat	str
single breakpoint	sbp
somatic mutation	sm
tandem repeat variant	trv
targeted gene analysis	tga
targeted sequence analysis	tsa
translocation analysis	ta
Variant	var

Jurisdiction 1 Part B

Molecular Diagnostic Services (MolDx) Program Frequently Asked Questions

Select the category of questions you would like to view:

Last updated: 12/2012

MolDx General Questions

1. What is the purpose of Palmetto GBA's MolDx program?
To identify tests, determine coverage, and determine reimbursement.

2. How does this program help Palmetto GBA adjudicate claims?
Once the required information is received and a unique identifier is assigned, Palmetto GBA can determine coverage and payment without documentation review. This process removes the need for the provider to submit large amounts of additional information with every claim and expedites claim payment.

3. What laboratories will be affected?
All private, reference, and hospital laboratories that perform molecular diagnostic testing and submit claims to Medicare in J1 on a CMS 1500 Claim Form or electronic claims on a 5010-837P are affected by this program.

4. What molecular diagnostic assays/tests are included in MolDx?
To help laboratory providers determine if a test should be registered for a unique identifier and submitted for a TA, see MolDx: 2013 HCPCS and CPT Code Changes. Submit questions about specific tests/assays not described in this chart, to MolDx@PalmettoGBA.com.

5. Is the MolDx Program national in scope?
Although the MolDx Program covers J1 (CA, NV, HI), labs that bill J1 services performed by a lab that is not located in J1 will have to register MDTs to identify the service.

6. Will this project align with the AMA effort to publish CPT codes for MDT?
The AMA efforts and the MolDx program are not related or interdependent.

7. How does a lab register a test?
Instructions are provided in MolDx Test Registration on the Palmetto GBA website.

8. What is the obligation or benefit to submit the MolDx Registration prior to the receipt of a coverage determination?
To identify the service and apply correct coverage for reimbursement.

9. What is McKesson's involvement in the MolDx program?
McKesson is the contracted technology provider for the MolDx program. Palmetto will leverage the McKesson Diagnostics ExchangeTM for the online test registry and tech assessment components of the MolDx program. The McKesson Diagnostics Exchange is a web-based service designed to identify tests and help establish transparent and evidence-based coverage for them. This tool enables labs to share test information with Palmetto GBA online.

10. What information will be made available to the public?
MolDx information collected for the registry will only be available to those labs electing to submit a Z-Code Identifier application and consistent with the public/private indications therein. Palmetto GBA has no plans to publish a PTI registry. Each data item represented by a spreadsheet column in the PTI and Z-Code

Identifier application is labeled with a public/private indicator. Only publicly available information will be visible in the registry for tests assigned a Z-Code Identifier.

11. Will Palmetto GBA expand the MolDx Program to other jurisdictions?
At this time Palmetto GBA has no indication that the MolDx program will be expanded. However, Palmetto GBA will administer active LCDs and articles published in J11.

MolDx Registration (PTI/Z-Code applications)

1. Is the Z-Code Identifier Application the only way to register a MolDx test?
No. Although we recommend that you apply for a Z-Code Identifier due to the additional benefits, including the on-line use and the Technical Assessment tool, Palmetto GBA added the Palmetto Test Identifier (PTI) as an alternate application method. See Palmetto Test Identifier (XLS, 75 KB) and a MolDx Test Information Form (XLS, 112 KB).

2. What is a Palmetto Test Identifier (PTI)?
A PTI is a unique identifier assigned to a test as an alternate to the Z-Code Identifier. Although both identifiers, the PTI and Z-Code, recognize a specific service and enable accurate coverage and reimbursement, Palmetto GBA recommends that laboratory providers submit Z-Code Identifier applications.

3. Why was the PTI added as an alternate unique identifier to the MolDx Program?
Palmetto GBA added this alternative in response to laboratory provider requests.

4. What is the difference between a PTI and a Z-Code Identifier?

- Z-Code Identifier
  - Unique identifier issued by McKesson associated with the test registration
  - May be used to identify tests outside the Palmetto GBA MolDx Program
  - Public information about the test and associated performing labs available through the McKesson Diagnostics ExchangeTM public registry
  - Allows access to the Technical Assessment(TA) Tool for online loading and tracking of submitted TAs
- PTI
  - Limited only to use with the Palmetto GBA MolDx Program
  - Public information about the test and associated performing labs is not on or available through the McKesson Diagnostics Exchange public registry
  - Palmetto GBA has exclusive use of the PTI and this identifier will only be used to recognize and apply coverage and reimbursement for claims submitted in the MolDx Program. The PTI and its supporting information will not appear or be used in the McKesson public registry.

5. Will the information collected through the PTI and Z-Code Identifier Applications be separately stored? Palmetto GBA has exclusive use of the PTI and this identifier will only be used to recognize and apply coverage and reimbursement for claims submitted in the MolDx Program. The PTI will not appear or be used in the public registry.

6. Should the manufacture or the performing lab register an FDA-approved, in vitro diagnostic test that utilizes a kit?
The manufacture and the performing labs should submit the application. The MolDx team will review each submission for accuracy and assign each performing lab that reports the test without modifications the same code. The lab must submit an application in order to obtain an identifier for submission. Without the application information, Palmetto GBA cannot determine the kit is unmodified.

7. Should the manufacturer also register for ASR's that have not been FDA approved?
No.

8. Why is the expiration date for CLIA certification on the unique identifier application? Will labs be required to update this field?
The unique identifier (PTI/Z-Code) applications have been revised to eliminate this field.

9. If multiple tests may be performed and billed within one assay, is the lab required to register

each test within the assay?
A unique identifier application is required for a single assay that may involve multiple tests to produce a single result.

10. Is a unique identifier application required for each specimen source, i.e. blood and bone marrow, for the same test?
If the billed codes used to report the test for the various specimen types are billed with the same codes, only a single unique identifier is necessary.

11. In addition to the unique identifier application, should labs send peer-reviewed articles to ensure Palmetto GBA has enough information to make a positive coverage determination?
No. Peer-reviewed literature used for coverage determination is only a requirement for the Technical Assessment (TA).

12. Is a unique identifier application required for an FDA-approved test?
The FDA approval process ensures the clinical and analytical validity of the test. However, the FDA does not include the review for clinical utility, which is required to establish Medicare coverage.

13. Will FISH ASR's included in the cytogentic studies require a unique identifier application?
No. See MolDx 2013 Code Changes.

14. Is a new unique identifier required for updated tests or a test expansion?
You will need to submit an application for the current test and for the new test, if it is substantively different. This applies if you plan to submit claims for the two different tests.

15. After a test is granted a unique identifier, can a hospital bill Palmetto or their respective MAC directly for the test using the assigned code?
No. The identifier is only used as additional information and may not be used as a substitute for a CPT/HCPCS code. However, hospitals may report the assigned unique identifier in the additional information field.

16. If a pathologist plans to submit a claim for the professional component of a MolDx test, should the pathologist register the test?
Yes.

17. Is a unique identifier required for tests billed with an NOC code?
Yes. See MolDx 2013 Code Changes.

18. Are labs expected to register tests sent to another lab to perform?
You are only required to register tests if you plan to submit claims to Palmetto GBA.

19. If a lab performs the same exact test from two different locations, operating under two different CLIA numbers, will the lab be required to submit both tests for unique identifiers?
If the test process is standardized and the same method is used to acquire the results in both locations, labs will only have to submit one application for the test. However, if there is a difference in the method, an application will be required from both locations.

20. Should labs that provide lab products alert their lab customers about MolDx registration requirements?
Yes.

21. If the kit used in an LDT is not FDA-approved, should the lab apply for a unique identifier for that kit?
Yes.

22. How do labs identify test reagents in the MolDx unique identifier application forms?
Enter the information in the 'contributing component' field.

23. Are labs required to register for a MolDx unique identifier on tests that use a stacking code and a code that is not listed in the MolDx range of codes (i.e., CPT codes 87001-87905)?
Yes.

24. I submitted a PTI application. Why was I assigned a Z-Code Identifier?

A PTI will only be issued for tests that have not been assigned a Z-Code Identifier. If Palmetto GBA receives a PTI application for a test with an existing or assigned Z-Code Identifier, a separate PTI will not be assigned (i.e., Test kit when the performed test has not been modified.) If a lab modifies a registered test, the resulting test is considered an LDT and will require a separate MolDx application.

Sample: A manufacture receives FDA approval for a kit and the kit is assigned a Z-code Identifier. If a lab performs and reports a test with the unmodified kit, the lab must use that Z-code Identifier. If the performing lab submits a PTI application for the unmodified test, Palmetto GBA will assign the same Z-Code Identifier assigned to the manufacture's test and will not assign a PTI. If the kit has been modified based on the application, a unique identifier will be assigned consistent with the lab's application (PTI or Z-Code Identifier).

Once an identifier has been assigned to the new LDT, a TA should be submitted.

25. What information will be made available to the public on the Palmetto GBA website?
MolDx information collected for the registry will only be available to those labs electing to submit a Z-Code Identifier application. Palmetto GBA has no plans to publish a PTI registry.

26. When a laboratory applies for a unique identifier, will the substance of its application be made available to the public?
Each data item represented by a spreadsheet column in the application is labeled with a public/private indicator. Only publicly available information will be visible in the registry for tests assigned with a Z-Code Identifier.

27. Will Palmetto GBA require a new unique identifier when a laboratory modifies an FDA approved kit?
Yes. If a lab modifies a registered test, the resulting test is considered an LDT and will require a separate application.

28. If a California laboratory is billing for a test referred to a laboratory located outside of the jurisdiction, which lab is responsible for submitting registering the test?
It is the responsibility of the billing provider to obtain a unique identifier.

29. If multiple laboratories purchase the same test and each lab registers the test, how will Palmetto GBA notify the laboratory regarding the assigned identifier?
Palmetto GBA will follow the registration process. Palmetto GBA will check the database for the unique identifier to ensure the test has not been submitted. If a test has been submitted, the lab will receive the assigned identifier. The only difference is the identifier has already been established by another entity prior to the current lab's application.

30. Will Palmetto GBA assign a cross-over PTI code for each Z-Code in order to create a complete code set for molecular diagnostic tests?
Palmetto GBA will not use the PTI and Z-Code Identifier to develop a code set. The identifiers provide specific information to enable Palmetto GBA to determine coverage and provide accurate reimbursement. Palmetto GBA will cross-reference each database.

31. Are hospital labs that file institutional claims and providers that file professional claims exempt from the requirement to obtain a unique identifier?
At this time the MolDx Program applies to J1 Part B claim submission. Part B includes professional claims or claims submitted by a pathologist for the professional component of a test. Therefore, a pathologist submitting claims for a professional MolDx service would be required to register a test.

Technical Assessment (TA)

1. The information requested by Palmetto GBA to support analytical validity may be considered proprietary intellectual property. How will Palmetto GBA assure the security and confidentiality of that information?
Only Palmetto GBA will review proprietary information.

2. Are there options in lieu of two published articles that support clinical utility?
In the absence of two published articles, Palmetto GBA will consider a single well-designed study with appropriate study subjects to establish significance, we will consider the following published documentation

in evaluating clinical utility:

- Retrospective studies
- White-papers written by national societies and recognized experts
- Virtual or theoretical models that have been vetted in the scientific literature
- Abstracts

The onus is on the laboratory provider to make their best case using any and all evidence to support clinical utility.

3. Who will perform the technical assessments (TA)?
Subject matter experts (SME) from academia and industry will assess the scientific literature. Palmetto GBA will perform the assessment for all other components.

4. Will Palmetto GBA share the conclusions of one SME with other SME?
No. A SME will only have access to their assigned TA. Also, each SME will only have access to the scientific literature submitted with the TA. All other components will be reviewed by Palmetto GBA. Only Palmetto GBA will review proprietary information.

5. What are the conflict of interest principles that will guide Palmetto GBA in determining whether or not an SME should be permitted to conduct a technical assessment?
The conflict of interest principles were developed by Blue Cross Blue Shield of South Carolina and are standard for the industry.

6. What types of disclosures will be required from the SMEs in order to facilitate a conflict of interest determination?
The disclosures required by the SME were developed by Blue Cross Blue Shield of South Carolina for government contractors and are standard for the industry.

7. Will there be an opportunity for a laboratory to comment on a TA report before it is finalized?
Yes. Questions/concerns that surface during the TA will be communicated with the test developer. However, once the determination has been made, Palmetto GBA will not reconsider a determination for six months after the initial determination. At that time the lab may submit another request if substantive 'new' information is available.

8. Will laboratories and/or manufacturers be allowed to resubmit a coverage request after they have received a non-coverage determination?
Yes. If a new request includes substantive new information that was not included in the initial request, the lab may submit anew request six months after the non-coverage determination was issued.

9. If the State of New York (NYS) has certified a test, does a lab need to submit the test for a MolDx TA?
No, if this is an industry accepted test. However, we may request the package used to determine the NYS certification to make a coverage decision. It is not our intent to burden laboratory providers. If you have received tech assessments through another entity, please submit this information through MolDx@PalmettoGBA.com.

10. What documentation is required to demonstrate the NYS approval for a test?
The approval letter or in the case of multiple test approvals, you may send a copy of your NYS listing.

11. What is the difference in the logistical steps to initiate a formal coverage determination and the process to initiate coverage determination with a TA?
It is the same process.

12. When a manufacturer has a new test approved under a PMA (which under FDA policy from the early '90s requires evidence of clinical utility) and the test is reported with the stacking codes, a unique identifier is required, but a TA is not. If the lab billed the same test with an NOC code, both a unique identifier and TA would be required.
The NOC is not the only considered fact about the TA. If, as in your example, a test is vetted for science and clinical utility, the information can be collected at the time the unique identifier is assigned. At that time the lab may bill the NOC with the assigned unique identifier. The issue, NOC code or stacking code, in some cases will be the data we may need to determine reimbursement.

13. Since the clinical and economic utility data will be reviewed as part of the coverage determination (and not during the TA), will our clinical utility evidence be sent out for subject matter expert review or will that evidence be reviewed within Palmetto GBA only? What about our economic utility evidence?
If the clinical utility and economic data are in the public domain (published), SME will review it. If it is proprietary, then Palmetto GBA will review it.

14. Is there a difference in the expected timeline for a coverage determination and a TA?
It is the same.

15. Is a MolDx test application required before a TA submission?
Yes.

16. Can a lab provide services prior to the TA approval date in anticipation of a favorable determination and then submit the claims after the approval?
To avoid overpayment requests, labs should freeze services until coverage is approved and appropriate billing and coding guidelines are published.

17. If a lab plans to submit a test for FDA approval, can the test be submitted for a TA first?
If the test is currently in the FDA process, please hold the TA request until the FDA has completed its determination. However, if you have not submitted the test to the FDA, you may request a TA. The FDA submission should be done prior to TA request. Once you receive an FDA determination, you may submit a TA request.

18. Should labs submit applications for Research Use Only Reagents (RUO)?
No.

19. Are manufactures that provide items such as ASR or RUO used in an LDT required to register the items?
No. Only the LDT developer and biller of the LDT are required to register for a unique identifier. However, an LDT developer must disclose the ASR and RUO used in the developed LDT on the application .

20. How should labs outline test reagents in the TA?
Submit the package insert for the kit with the materials.

21. When multiple large numbers of reagents are used in a test, how should labs identify the specific details for the reagents?
Provide sufficient information to identify the manufacturer and the product specifications (PI).

22. Should protocols for technical evaluation be included in the TA submission?
Yes.

23. Will a completed TA be made available on the Palmetto GBA website?
Only an approved TA will be published. However, Palmetto GBA may publish a coverage/non-coverage article or an LCD based on the TA.

24. How should a laboratory designate proprietary information on the TA submission?
Palmetto GBA will consider any information that is not publicly available to be proprietary information.

25. Will Palmetto GBA make components of the TA available to the public?
Only information that is publicly available from the manufacture’s website will be available through the TA software. Only the final approval synopsis will be published. Proprietary information will not be included in this summary.

26. During the TA process, when should a laboratory submit pricing information to support a payment rate determination?
The instructions for the TA are published on Palmetto GBA’s website.

27. When will Palmetto GBA make the pricing determination?
A pricing determination will be made once the TA is complete and the service is determined to be reasonable and necessary for Medicare beneficiaries.

28. How will Palmetto GBA determine reimbursement for a test?

Reimbursement is based on accurate submitted codes regardless of the cost of the platform used. For tests that are reported with an NOC code, pricing will be determined based on the information collected in the TA. Each test will be assessed on an individual basis and priced according to the most appropriate method. Palmetto GBA will review the pricing method with the individual lab upon completion of the TA.

29. When should labs submit the clinical data dossier (TA) to Palmetto GBA?
Palmetto GBA will accept a TA after an identifier has been assigned. For labs that do not submit the clinical data, Palmetto GBA will prioritize according to claims data and make requests.

30. If a test requires a TA and is performed by a laboratory outside Palmetto GBA's jurisdiction that does not bill Palmetto GBA directly, how is the TA submission to be completed?
In order to receive a coverage determination, it is the responsibility of the billing laboratory to submit a TA. Claims paid for tests that do not meet the mandated reasonable and necessary criteria may be subject to overpayment requests.

Billing and Coding

1. Can labs continue to bill the stacking codes once the unique identifier is assigned?

- If the assay was billed prior to assignment, you may continue with the same stack and the unique identifier in the comment/narrative field
- If the assay has never been billed, you must submit a TA and a coverage determination prior to submission

2. What are the effective dates of the codes ZSB01 and ZB728?
Z-Code Identifiers are effective at time of assignment.

3. What action should a lab take if they believe they may have incorrectly billed for a MolDx service?
If you believe your practice has made a MolDx billing/coding error, you may take the following corrective actions:

- Complete a Self-Audit
  - Identify incorrect submissions
  - Contain further claim submission errors
- Consider Self-Disclosure Protocol
  - Self-disclosure guidelines available on the OIG website

4. Where do I enter the assigned MolDx test identifier on my claim?
If you are submitting a paper claim, this information would be placed in Block 19 of the CMS 1500 claim form. For Electronic claims (5010):

- 837P (Physician/Professional)

Use the SV101-7 to provide the unique identifier for all lines related to the test indicated by the identifier. This field maps to the Line item Description (This field is required for NOC codes to avoid rejection by the Common Edit Module Front end).

5. If the lab submits a MolDx covered test without a unique identifier after the implementation date, will Palmetto GBA reject the claim as 'unprocessable' with no appeal rights or send a denial with a specific or new claim denial message?
Claims received without additional information required to adjudicate the claim will be rejected.

6. If a laboratory performs multiple assays/tests on a single patient on one date of service, will the lab have to split the different assays/tests into multiple claims?
No. Laboratory providers may submit multiple assays per claim. The SV701-7 narrative field on the 837P claim is limited to one unique identifier per claim line. Therefore, you must report the complete code stack and unique identifier for each test. In many cases this will require labs to repeat a CPT code on the claim and append with the 91 CPT modifier to indicate the additional service(s) is not a duplicate.

Claim Example

Performed Test	CPT code/modifier	Number of	Unique

		Service (NOS)	Identifier
Assay 1	83890-91	1	P1234
Assay 1	83893-91	5	P1234
Assay 2	83890-91	1	P6789
Assay 2	83893-91	3	P6789

7. If a CPT code appears on the claim more than once to report an additional test, is a modifier required?
Yes. Append with CPT modifier 91. See the claim example for question 8.

8. Will CCI edits continue to be in effect on MolDx services?
Yes. Because the PTI/Z-Code Identifier only acts to label the specific test and are not a code set, MolDx service providers must append CPT codes within the CCI edits with a 59 CPT modifier to indicate the CCI Column II code is a different test.

Example:

Performed Test	CPT code/modifier	Number of Service (NOS)	Unique Identifier
Assay 1	88386	1	P1234
Assay 2	83903-59	1	P6789
Assay 2	83891	1	P6789
Assay 2	83896-59	2	P6789
Assay 2	83898	1	P6789
Assay 2	83912-59	1	P6789

Note: The 59 CPT modifier should ONLY be appended to CCI Column II codes.

9. There is only one Box 19 on my paper claim form. How do I identify more than one test or assay on my claim?
Answer: Due to the limitations of the paper claim, labs using this form will be limited to only one test/assay/unique identifier per claim. To bill a MolDx test on a paper claim, enter the unique identifier in Box 19 and then enter only the stack for that identifier on the claim. Remember: You may only file one test per paper claim submission.

Reimbursement

1. Will a microarray service be reimbursed at the same rate for all microarrays or will the diagnosis differentiate payment? For example, will 1800+ genes of one array be viewed differently than an 1800+ array with a different algorithm?
Diagnosis will not differentiate payment. Payment is based on the accurate CPT/HCPCS codes submitted. However, if there are less than 500 probes in an array, CPT code 83999 must be used and Palmetto GBA will price the NOC code.

2. Does the DRG segregate the CPT code to a different payment?
No.

3. If a test produces similar results, but is performed on different platforms with different costs, will the reimbursement rate be adjusted to show the increase in platform costs?
Reimbursement is based on accurate submitted codes regardless of the cost of the platform used.

4. Will ABN's be valid with the unique identifier?
The unique identifier is only additional information not a billing code.

5. Will Palmetto GBA pay test services provided prior to the TA approval date?
Prior to the TA, claims will process according to the billed services. If information in the TA indicates a non-

covered service or inappropriate billing, Palmetto GBA will make the appropriate corrections.

6. If I already have a PTI for my test, how do I switch to a Z-Code Identifier so I can use the online TA feature?
Send a request to switch the ID to MolDx@PalmettoGBA.com.

7. Is the reimbursement for a flow cytometry affected by MolDx?
Palmetto GBA has an active LCD for Flow Cytometry and will continue to administer coverage as published in that policy and any other active policy.

Coverage Issues
1. Is a confirmatory FISH test a covered benefit?
Confirmatory testing is considered a quality check and is not a covered Medicare benefit.

2. If a lab needs a denial for a noncovered test in order to bill a secondary payor, should they submit the test for MolDx registration?
Yes.

last updated on 12/20/2012
ver 1.0.37

^ Back to Top

MolDX Home / Frequently Asked Questions / Molecular Diagnostic Services (MolDX) Program Frequently Asked Questions
MolDX
Molecular Diagnostic Services (MolDX) Program Frequently Asked Questions

Select the category of questions you would like to view:

Last updated: 09/23/2013

MolDX General Questions

1. What is the purpose of Palmetto GBA's MolDX program?
To identify tests, determine coverage, and determine reimbursement.

2. How does this program help Palmetto GBA adjudicate claims?
Once the required information is received and a unique identifier is assigned, Palmetto GBA can determine coverage and payment without documentation review. This process removes the need for the provider to submit large amounts of additional information with every claim and expedites claim payment.

3. What laboratories will be affected?
All private, reference, and hospital laboratories that perform molecular diagnostic testing and submit claims to Medicare in JE on a CMS 1500 Claim Form or electronic claims on a 5010-837P are affected by this program.

4. What molecular diagnostic assays/tests are included in MolDX?
To help laboratory providers determine if a test should be registered for a unique identifier and submitted for a TA, see MolDX: 2013 HCPCS and CPT Code Changes. Submit questions about specific tests/assays not described in this chart, to MolDX@PalmettoGBA.com.

5. Is the MolDX Program national in scope?
Although the MolDX Program covers JE (CA, NV, HI), labs that bill JE services performed by a lab that is not located in JE will have to register MDTs to identify the service. With the finalization of the MDT policy, effective October 18, 2013, in J11, MolDX will also cover NC, SC, VA and WV.

6. Will this project align with the AMA effort to publish CPT codes for MDT?
The AMA efforts and the MolDX program are not related or interdependent.

7. How does a lab register a test?
Instructions are provided in MolDX Test Registration on the MolDX website.

8. What is the obligation or benefit to submit the MolDX Registration prior to the receipt of a coverage determination?
To identify the service and apply correct coverage for reimbursement.

9. What is McKesson's involvement in the MolDX program?
McKesson is the contracted technology provider for the MolDX program. Palmetto will leverage the McKesson Diagnostics Exchange(TM) for the online test registry and tech assessment components of the MolDX program. The McKesson Diagnostics Exchange is a Web-based service designed to identify tests and help establish transparent and evidence-based coverage for them. This tool enables labs to share test information with Palmetto GBA online.

10. What information will be made available to the public?
MolDX information collected for the registry will only be available to those labs electing to submit a Z-Code Identifier application and consistent with the public/private indications therein. Palmetto GBA has no plans to publish a PTI registry. Each data item represented by a spreadsheet column in the PTI and Z-Code Identifier

application is labeled with a public/private indicator. Only publicly available information will be visible in the registry for tests assigned a Z-Code Identifier.

11. Will Palmetto GBA expand the MolDX Program to other jurisdictions?
At this time Palmetto GBA has no indication that the MolDX program will be expanded. However, Palmetto GBA will administer active LCDs and articles published in J11 and Noridian will administer the MolDX Program in JE.

MolDX Registration (PTI/Z-Code applications)

1. Is the Z-Code Identifier Application the only way to register a MolDX test?
No. Although we recommend that you apply for a Z-Code Identifier due to the additional benefits, including the on-line use and the Technical Assessment tool, Palmetto GBA added the Palmetto Test Identifier (PTI) as an alternate application method. See Palmetto Test Identifier (XLS, 75 KB) and a MolDX Test Information Form (XLS, 112 KB). Please note that the PTI assignment is a manual process and Palmetto GBA cannot maintain the 30-day turnaround offered by the online registry. To avoid delays, we encourage labs to use the online registry.

2. What is a Palmetto Test Identifier (PTI)?
A PTI is a unique identifier assigned to a test as an alternate to the Z-Code Identifier. Although both identifiers, the PTI and Z-Code, recognize a specific service and enable accurate coverage and reimbursement, Palmetto GBA recommends that laboratory providers submit Z-Code Identifier applications.

3. Why was the PTI added as an alternate unique identifier to the MolDX Program?
Palmetto GBA added this alternative in response to laboratory provider requests.

4. What is the difference between a PTI and a Z-Code Identifier?

- Z-Code Identifier
  - Unique identifier issued by McKesson associated with the test registration
  - May be used to identify tests outside the Palmetto GBA MolDX Program
  - Public information about the test and associated performing labs available through the McKesson Diagnostics ExchangeTM public registry
  - Allows access to the Technical Assessment(TA) Tool for online loading and tracking of submitted TAs
- PTI
  - Limited only to use with the Palmetto GBA MolDX Program
  - Public information about the test and associated performing labs is not on or available through the McKesson Diagnostics Exchange public registry
  - Palmetto GBA has exclusive use of the PTI and this identifier will only be used to recognize and apply coverage and reimbursement for claims submitted in the MolDX Program. The PTI and its supporting information will not appear or be used in the McKesson public registry.

5. Will the information collected through the PTI and Z-Code Identifier Applications be separately stored? Palmetto GBA has exclusive use of the PTI and this identifier will only be used to recognize and apply coverage and reimbursement for claims submitted in the MolDX Program. The PTI will not appear or be used in the public registry.

6. Should the manufacture or the performing lab register an FDA-approved, in vitro diagnostic test that utilizes a kit?
The manufacture and the performing labs should submit the application. The MolDX team will review each submission for accuracy and assign each performing lab that reports the test without modifications the same code. The lab must submit an application in order to obtain an identifier for submission. Without the application information, Palmetto GBA cannot determine the kit is unmodified.

7. Should the manufacturer also register for ASR's that have not been FDA approved?
No.

8. Why is the expiration date for CLIA certification on the unique identifier application? Will labs be required to update this field?
The unique identifier (Z-Code) applications have been revised to eliminate this field.

9. If multiple tests may be performed and billed within one assay, is the lab required to register

each test within the assay?
A unique identifier application is required for a single assay that may involve multiple tests to produce a single result.

10. Is a unique identifier application required for each specimen source, i.e. blood and bone marrow, for the same test?
If the billed codes used to report the test for the various specimen types are billed with the same codes, only a single unique identifier is necessary.

11. In addition to the unique identifier application, should labs send peer-reviewed articles to ensure Palmetto GBA has enough information to make a positive coverage determination?
No. Peer-reviewed literature used for coverage determination is only a requirement for the Technical Assessment (TA).

12. Is a unique identifier application required for an FDA-approved test?
The FDA approval process ensures the clinical and analytical validity of the test. However, the FDA does not include the review for clinical utility, which is required to establish Medicare coverage.

13. Will FISH ASR's included in the cytogentic studies require a unique identifier application?
No. See MolDX 2013 Code Changes.

14. Is a new unique identifier required for updated tests or a test expansion?
You will need to submit an application for the current test and for the new test, if it is substantively different. This applies if you plan to submit claims for the two different tests.

15. After a test is granted a unique identifier, can a hospital bill Palmetto or their respective MAC directly for the test using the assigned code?
No. The identifier is only used as additional information and may not be used as a substitute for a CPT/HCPCS code. However, hospitals may report the assigned unique identifier in the additional information field.

16. If a pathologist plans to submit a claim for the professional component of a MolDX test, should the pathologist register the test?
Yes.

17. Is a unique identifier required for tests billed with an NOC code?
Yes. See MolDX 2013 Code Changes.

18. Are labs expected to register tests sent to another lab to perform?
You are only required to register tests if you plan to submit claims to Palmetto GBA.

19. If a lab performs the same exact test from two different locations, operating under two different CLIA numbers, will the lab be required to submit both tests for unique identifiers?
If the test process is standardized and the same method is used to acquire the results in both locations, labs will only have to submit one application for the test. However, if there is a difference in the method, an application will be required from both locations.

20. Should labs that provide lab products alert their lab customers about MolDX registration requirements?
Yes.

21. If the kit used in an LDT is not FDA-approved, should the lab apply for a unique identifier for that kit?
Yes.

22. How do labs identify test reagents in the MolDX unique identifier application forms?
Enter the information in the 'contributing component' field.

23. Are labs required to register for a MolDX unique identifier on tests that use a stacking code and a code that is not listed in the MolDX range of codes (i.e., CPT codes 87001-87905)?
Yes.

24. I submitted a PTI application. Why was I assigned a Z-Code Identifier?

A PTI will only be issued for tests that have not been assigned a Z-Code Identifier. If Palmetto GBA receives a PTI application for a test with an existing or assigned Z-Code Identifier, a separate PTI will not be assigned (i.e., Test kit when the performed test has not been modified.) If a lab modifies a registered test, the resulting test is considered an LDT and will require a separate MolDX application.

Sample: A manufacture receives FDA approval for a kit and the kit is assigned a Z-code Identifier. If a lab performs and reports a test with the unmodified kit, the lab must use that Z-code Identifier. If the performing lab submits a PTI application for the unmodified test, Palmetto GBA will assign the same Z-Code Identifier assigned to the manufacture's test and will not assign a PTI. If the kit has been modified based on the application, a unique identifier will be assigned consistent with the lab's application (PTI or Z-Code Identifier).

Once an identifier has been assigned to the new LDT, a TA should be submitted.

25. What information will be made available to the public on the Palmetto GBA website?
MolDX information collected for the registry will only be available to those labs electing to submit a Z-Code Identifier application. Palmetto GBA has no plans to publish a PTI registry.

26. When a laboratory applies for a unique identifier, will the substance of its application be made available to the public?
Each data item represented by a spreadsheet column in the application is labeled with a public/private indicator. Only publicly available information will be visible in the registry for tests assigned with a Z-Code Identifier.

27. Will Palmetto GBA require a new unique identifier when a laboratory modifies an FDA approved kit?
Yes. If a lab modifies a registered test, the resulting test is considered an LDT and will require a separate application.

28. If a California laboratory is billing for a test referred to a laboratory located outside of the jurisdiction, which lab is responsible for submitting registering the test?
It is the responsibility of the billing provider to obtain a unique identifier.

29. If multiple laboratories purchase the same test and each lab registers the test, how will Palmetto GBA notify the laboratory regarding the assigned identifier?
Palmetto GBA will follow the registration process. Palmetto GBA will check the database for the unique identifier to ensure the test has not been submitted. If a test has been submitted, the lab will receive the assigned identifier. The only difference is the identifier has already been established by another entity prior to the current lab's application.

30. Will Palmetto GBA assign a cross-over PTI code for each Z-Code in order to create a complete code set for molecular diagnostic tests?
Palmetto GBA will not use the PTI and Z-Code Identifier to develop a code set. The identifiers provide specific information to enable Palmetto GBA to determine coverage and provide accurate reimbursement. Palmetto GBA will cross-reference each database.

31. Are hospital labs that file institutional claims and providers that file professional claims exempt from the requirement to obtain a unique identifier?
At this time the MolDX Program applies to JE Part B claim submission. Part B includes professional claims or claims submitted by a pathologist for the professional component of a test. Therefore, a pathologist submitting claims for a professional MolDX service would be required to register a test.

Technical Assessment (TA)

1. The information requested by Palmetto GBA to support analytical validity may be considered proprietary intellectual property. How will Palmetto GBA assure the security and confidentiality of that information?
Only Palmetto GBA will review proprietary information.

2. Are there options in lieu of two published articles that support clinical utility?
In the absence of two published articles, Palmetto GBA will consider a single well-designed study with appropriate study subjects to establish significance, we will consider the following published documentation in evaluating clinical utility:

- Retrospective studies
- White-papers written by national societies and recognized experts
- Virtual or theoretical models that have been vetted in the scientific literature
- Abstracts

The onus is on the laboratory provider to make their best case using any and all evidence to support clinical utility.

3. Who will perform the technical assessments (TA)?
Subject matter experts (SME) from academia and industry will assess the scientific literature. Palmetto GBA will perform the assessment for all other components.

4. Will Palmetto GBA share the conclusions of one SME with other SME?
No. A SME will only have access to their assigned TA. Also, each SME will only have access to the scientific literature submitted with the TA. All other components will be reviewed by Palmetto GBA. Only Palmetto GBA will review proprietary information.

5. What are the conflict of interest principles that will guide Palmetto GBA in determining whether or not an SME should be permitted to conduct a technical assessment?
The conflict of interest principles were developed by Blue Cross Blue Shield of South Carolina and are standard for the industry.

6. What types of disclosures will be required from the SMEs in order to facilitate a conflict of interest determination?
The disclosures required by the SME were developed by Blue Cross Blue Shield of South Carolina for government contractors and are standard for the industry.

7. Will there be an opportunity for a laboratory to comment on a TA report before it is finalized?
Yes. Questions/concerns that surface during the TA will be communicated with the test developer. However, once the determination has been made, Palmetto GBA will not reconsider a determination for six months after the initial determination. At that time the lab may submit another request if substantive 'new' information is available.

8. Will laboratories and/or manufacturers be allowed to resubmit a coverage request after they have received a non-coverage determination?
Yes. If a new request includes substantive new information that was not included in the initial request, the lab may submit anew request six months after the non-coverage determination was issued.

9. If the State of New York (NYS) has certified a test, does a lab need to submit the test for a MolDX TA?
No, if this is an industry accepted test. However, we may request the package used to determine the NYS certification to make a coverage decision. It is not our intent to burden laboratory providers. If you have received tech assessments through another entity, please submit this information through MolDX@PalmettoGBA.com.

10. What documentation is required to demonstrate the NYS approval for a test?
The approval letter or in the case of multiple test approvals, you may send a copy of your NYS listing.

11. What is the difference in the logistical steps to initiate a formal coverage determination and the process to initiate coverage determination with a TA?
It is the same process.

12. When a manufacturer has a new test approved under a PMA (which under FDA policy from the early '90s requires evidence of clinical utility) and the test is reported with the stacking codes, a unique identifier is required, but a TA is not. If the lab billed the same test with an NOC code, both a unique identifier and TA would be required.
The NOC is not the only considered fact about the TA. If, as in your example, a test is vetted for science and clinical utility, the information can be collected at the time the unique identifier is assigned. At that time the lab may bill the NOC with the assigned unique identifier. The issue, NOC code or stacking code, in some cases will be the data we may need to determine reimbursement.

13. Since the clinical and economic utility data will be reviewed as part of the coverage determination (and not during the TA), will our clinical utility evidence be sent out for subject

matter expert review or will that evidence be reviewed within Palmetto GBA only? What about our economic utility evidence?
If the clinical utility and economic data are in the public domain (published), SME will review it. If it is proprietary, then Palmetto GBA will review it.

14. Is there a difference in the expected timeline for a coverage determination and a TA?
It is the same.

15. Is a MolDX test application required before a TA submission?
Yes.

16. Can a lab provide services prior to the TA approval date in anticipation of a favorable determination and then submit the claims after the approval?
To avoid overpayment requests, labs should freeze services until coverage is approved and appropriate billing and coding guidelines are published.

17. If a lab plans to submit a test for FDA approval, can the test be submitted for a TA first?
If the test is currently in the FDA process, please hold the TA request until the FDA has completed its determination. However, if you have not submitted the test to the FDA, you may request a TA. The FDA submission should be done prior to TA request. Once you receive an FDA determination, you may submit a TA request.

18. Should labs submit applications for Research Use Only Reagents (RUO)?
No.

19. Are manufactures that provide items such as ASR or RUO used in an LDT required to register the items?
No. Only the LDT developer and biller of the LDT are required to register for a unique identifier. However, an LDT developer must disclose the ASR and RUO used in the developed LDT on the application .

20. How should labs outline test reagents in the TA?
Submit the package insert for the kit with the materials.

21. When multiple large numbers of reagents are used in a test, how should labs identify the specific details for the reagents?
Provide sufficient information to identify the manufacturer and the product specifications (PI).

22. Should protocols for technical evaluation be included in the TA submission?
Yes.

23. Will a completed TA be made available on the Palmetto GBA website?
Only an approved TA will be published. However, Palmetto GBA may publish a coverage/non-coverage article or an LCD based on the TA.

24. How should a laboratory designate proprietary information on the TA submission?
Palmetto GBA will consider any information that is not publicly available to be proprietary information.

25. Will Palmetto GBA make components of the TA available to the public?
Only information that is publicly available from the manufacture's website will be available through the TA software. Only the final approval synopsis will be published. Proprietary information will not be included in this summary.

26. During the TA process, when should a laboratory submit pricing information to support a payment rate determination?
The instructions for the TA are published on Palmetto GBA's website.

27. When will Palmetto GBA make the pricing determination?
A pricing determination will be made once the TA is complete and the service is determined to be reasonable and necessary for Medicare beneficiaries.

28. How will Palmetto GBA determine reimbursement for a test?
Reimbursement is based on accurate submitted codes regardless of the cost of the platform used. For tests that are reported with an NOC code, pricing will be determined based on the information collected in the TA.

Each test will be assessed on an individual basis and priced according to the most appropriate method. Palmetto GBA will review the pricing method with the individual lab upon completion of the TA.

29. When should labs submit the clinical data dossier (TA) to Palmetto GBA?
Palmetto GBA will accept a TA after an identifier has been assigned. For labs that do not submit the clinical data, Palmetto GBA will prioritize according to claims data and make requests.

30. If a test requires a TA and is performed by a laboratory outside Palmetto GBA's jurisdiction that does not bill Palmetto GBA directly, how is the TA submission to be completed?
In order to receive a coverage determination, it is the responsibility of the billing laboratory to submit a TA. Claims paid for tests that do not meet the mandated reasonable and necessary criteria may be subject to overpayment requests.

31. Why was an invalid determination issues on my TA submission?
TA must be submitted with the test ID in the subject line. Palmetto GBA will not initiate a TA without an ID. Additionally, all communication regarding tests must have the ID in the subject line. This enables the MolDX staff to accurately track your test documents and avoid unnecessary delays and documentation misplacement.

Billing and Coding

1. What are the effective dates of the codes ZSB01 and ZB728?
Z-Code Identifiers are effective at time of assignment.

2. What action should a lab take if they believe they may have incorrectly billed for a MolDX service?
If you believe your practice has made a MolDX billing/coding error, you may take the following corrective actions:

- Complete a Self-Audit
  - Identify incorrect submissions
  - Contain further claim submission errors
- Consider Self-Disclosure Protocol
  - Self-disclosure guidelines available on the OIG website

3. Where do I enter the assigned MolDX test identifier on my claim?
If you are submitting a paper claim, this information would be placed in Block 19 of the CMS 1500 claim form. For Electronic claims (5010):

- 837P (Physician/Professional)

Use the SV101-7 to provide the unique identifier for all lines related to the test indicated by the identifier. This field maps to the Line item Description (This field is required for NOC codes to avoid rejection by the Common Edit Module Front end).

4. If the lab submits a MolDX covered test without a unique identifier after the implementation date, will Palmetto GBA reject the claim as 'unprocessable' with no appeal rights or send a denial with a specific or new claim denial message?
Claims received without additional information required to adjudicate the claim will be rejected.

5. If a laboratory performs multiple assays/tests on a single patient on one date of service, will the lab have to split the different assays/tests into multiple claims?
No. Laboratory providers may submit multiple assays per claim. The SV701-7 narrative field on the 837P claim is limited to one unique identifier per claim line. Therefore, you must report the complete code stack and unique identifier for each test. In many cases this will require labs to repeat a CPT code on the claim and append with the 91 CPT modifier to indicate the additional service(s) is not a duplicate.

Claim Example

Performed Test	CPT code/modifier	Number of Service (NOS)	Unique Identifier
Assay 1	81200	1	Z1234

Assay 2	81401	1	Z6789
Assay 3	81401-91	1	Z8889

6. If a CPT code appears on the claim more than once to report an additional test, is a modifier required?
Yes. Append with CPT modifier 91. See the claim example for question 8.

7. How do I submit a claim for only the professional interpretation of a test?
In the rare instance when an additional and separate professional interpretation is needed, the pathologist will need to obtain the ID for the interpreted test from the performing lab.

8. Will CCI edits continue to be in effect on MolDX services?
Yes. Because the Z-Code Identifier only acts to label the specific test and is not a code set, MolDX service providers must append CPT codes within the CCI edits with a 59 CPT modifier to indicate the CCI Column II code is a different test.

Note: The 59 CPT modifier should ONLY be appended to CCI Column II codes.

9. There is only one Box 19 on my paper claim form. How do I identify more than one test or assay on my claim?
Due to the limitations of the paper claim, labs using this form will be limited to only one test/assay/unique identifier per claim. To bill a MolDX test on a paper claim, enter the unique identifier in Box 19 and then enter only the stack for that identifier on the claim. Remember: You may only file one test per paper claim submission.

Reimbursement

1. Will a microarray service be reimbursed at the same rate for all microarrays or will the diagnosis differentiate payment? For example, will 1800+ genes of one array be viewed differently than an 1800+ array with a different algorithm?
Diagnosis will not differentiate payment. Payment is based on the accurate CPT/HCPCS codes submitted. However, if there are less than 500 probes in an array, CPT code 83999 must be used and Palmetto GBA will price the NOC code.

2. Does the DRG segregate the CPT code to a different payment?
No.

3. If a test produces similar results, but is performed on different platforms with different costs, will the reimbursement rate be adjusted to show the increase in platform costs?
Reimbursement is based on accurate submitted codes regardless of the cost of the platform used.

4. Will ABN's be valid with the unique identifier?
The unique identifier is only additional information not a billing code.

5. Will Palmetto GBA pay test services provided prior to the TA approval date?
Prior to the TA, claims will process according to the billed services. If information in the TA indicates a non-covered service or inappropriate billing, Palmetto GBA will make the appropriate corrections.

6. If I already have a PTI for my test, how do I switch to a Z-Code Identifier so I can use the online TA feature?
Send a request to switch the ID to MolDX@PalmettoGBA.com.

7. Is the reimbursement for a flow cytometry affected by MolDX?
Palmetto GBA has an active LCD for Flow Cytometry and will continue to administer coverage as published in that policy and any other active policy.

Coverage Issues
1. Is a confirmatory FISH test a covered benefit?
Confirmatory testing is considered a quality check and is not a covered Medicare benefit.

2. If a lab needs a denial for a noncovered test in order to bill a secondary payor, should they submit the test for MolDX registration?
Yes.

last updated on 09/23/2013

ver 1.0.0

^ Back to Top
Palmetto GBA CorporatePalmetto GBA Medicare
Palmetto GBA Home / Jurisdiction 1 Part B / Browse by Topic / MolDx

Accesed 07/08/2013
NOTE: The highlights identify items that were changed/updated/deleted after this date.

Jurisdiction 1 Part B

MolDx

Need help finding what you are looking for on this page?

Select a Topic: Please Select

Page 1 of 1 see 25 | see 50 | see 100 Search this Area

MolDx: Vectra DA Coding and Billing Guidelines New!	07/02/2013
MolDx: PIK3CA Gene Tests Coding and Billing Guidelines	06/28/2013
2013 Palmetto GBA MoPath Fee Schedule and Claim Submission Guidelines	06/26/2013
MolDx: STAT3 Gene Testing Coding and Billing Guidelines	06/26/2013
MolDx: CHD7 Gene Analysis Coding and Billing Guidelines	06/25/2013
MolDx: HTTLPR Gene Testing Coding and Billing Guidelines	06/25/2013
MolDx: MPL Gene Tests Coding and Billing Guidelines	06/25/2013
MolDx: NSD1 Gene Tests Coding and Billing Guidelines	06/25/2013
MolDx: PTCH1 Gene Testing Coding and Billing Guidelines	06/25/2013
MolDx: RPS19 Gene Tests Coding and Billing Guidelines	06/25/2013
MolDx: TERC Gene Tests Coding and Billing Guidelines	06/25/2013
MolDx: HBB Full Gene Sequencing Coding and Billing Guidelines	06/24/2013
MolDx: TP53 Gene Test Coding and Billing Guidelines	06/24/2013
Specimen Validity Testing	06/20/2013
MolDx: BCR-ABL Coding and Billing Guidelines Update	06/19/2013
MolDx: CYP2C9 and/or VKORC1 Gene Testing for Warfarin Response Coding and Billing Guidelines	06/05/2013
MolDx: Oncotype DX Breast Cancer Assay Coding and Billing Guidelines	05/08/2013
MolDx: therascreen KRAS PCR Kit Billing/Coding Guidelines	04/29/2013
Molecular Diagnostic Services Program (MolDx) Coverage Determination Process	04/16/2013
MolDx: CellSearch Coding and Billing Guidelines	03/19/2013
MolDx: 2013 HCPCS and CPT Code Changes	03/06/2013
MolDx: UGT1A1 Gene Analysis Coding and Billing Guidelines	02/27/2013
MolDx: bioTheranostics Cancer TYPE ID Coding and Billing Guidelines	02/21/2013
MolDx: MECP2 Genetic Testing Coding and Billing Guidelines	02/19/2013
MolDx: Arrhythmogenic Right Ventricular Dysplasia/Cardiomyopathy (ARVD/C) Testing Coding and Billing Guidelines	02/07/2013
MolDx: Aspartoacyclase 2 Deficiency Testing Coding and Billing Guidelines	02/07/2013
MolDx: BCKDHB Gene Test Coding and Billing Guidelines	02/07/2013

MolDx: HEXA Gene Analysis Coding and Billing Guidelines	02/07/2013
MolDx: IKBKAP Genetic Testing Coding and Billing Guidelines	02/07/2013
MolDx: SMPD1 Genetic Testing Coding and Billing Guidelines	02/07/2013
MolDx: BLM Gene Analysis Coding and Billing Guidelines	02/06/2013
MolDx: FANCC Genetic Testing Coding and Billing Guidelines	02/06/2013
MolDx: GBA Genetic Testing Coding and Billing Guidelines	02/06/2013
MolDx: HAX1 Gene Sequencing Coding and Billing Guidelines	02/06/2013
MolDx: MCOLN1 Genetic Testing Coding and Billing Guidelines	02/06/2013
MolDx: CFTR Gene Analysis Coding and Billing Guidelines	02/05/2013
MolDx: Fragile X Coding and Billing Guidelines	01/31/2013
MolDx: L1CAM Gene Sequencing Coding and Billing Guidelines	01/29/2013
MolDx: Mitochondrial Nuclear Gene Tests Coding and Billing Guidelines	01/29/2013
MolDx: PAX6 Gene Sequencing Coding and Billing Guidelines	01/29/2013
Technical Assessment (TA) Process	01/08/2013
MolDx: 4q25-AF Risk Genotype Coding and Billing Guidelines	01/07/2013
MolDx: 9p21 Genotype Test Coding and Billing Guidelines	01/07/2013
MolDx: ApoE Genotype Coding and Billing Guidelines	01/07/2013
MolDx: BluePrint Coding and Billing Guidelines	01/07/2013
MolDx: KIF6 Genotype Coding and Billing Guidelines	01/07/2013
MolDx: LPA-Aspirin Genotype Coding and Billing Guidelines	01/07/2013
MolDx: LPA-Intron 25 Genotype Coding and Billing Guidelines	01/07/2013
MolDx: Pervenio Lung RS Assay Coding and Billing Guidelines	01/07/2013
MolDx: PreDx Coding and Billing Guidelines	01/07/2013
MolDx: Prostate Molecular Markers Coding and Billing Guidelines	01/07/2013
MolDx: SLCO1B1 Genotype Coding and Billing Guidelines	01/07/2013
MolDx: Cytogenomic Constitutional Microarray Analysis Coding and Billing Guidelines	01/02/2013
MolDx: Septin 9 Methylated DNA Test Coding and Billing Guidelines	12/21/2012
MolDx: Physicians Providing MolDx Services	12/20/2012
Molecular Diagnostic Services (MolDx) Program Frequently Asked Questions	12/20/2012
MolDx Test Registration	12/14/2012
Molecular Diagnostic Services (MolDx) Program	12/13/2012
MolDx: Vysis Kit by Abbott Coding and Billing Guidelines	12/12/2012
MolDx: Web Page Search Tool	12/10/2012
MolDx: know error Coding and Billing Guidelines	11/07/2012
MolDx: Coverage with Evidence Development	10/31/2012
MolDx: Progensa PCA3 Assay Coding and Billing Guidelines	09/11/2012
MolDx: cobas 4800 BRAF V600 Test Coding and Billing Guidelines	09/07/2012
MolDx: Corus CAD Test Coding and Billing Guidelines	08/07/2012
MolDx: OncoCee Coding and Billing Guidelines	08/07/2012
The MolDx online technical assessment process is now available!	07/19/2012

Attachment E: Copies of MolDX web pages - posted in the past

Exciting news from the MolDx Team at Palmetto GBA!	07/16/2012
MolDx: Oncotype DX Colon Cancer Assay Coding and Billing Guidelines	06/28/2012
MolDx: Avise PG Assay Coding and Billing Guidelines	05/24/2012
MolDx: Pathwork Tissue of Origin Test Coding and Billing Guidelines	04/26/2012
MolDX: HERmark Assay by Monogram Coding and Billing Guidelines	04/23/2012
MolDx: MammaPrint Billing and Coding Guidelines Update	03/12/2012
MolDx: AlloMap Coding and Billing Guidelines	03/07/2012
MolDx: Afirma Assay by Veracyte Coding and Billing Guidelines	03/05/2012

see 25 | see 50 | see 100

last updated on 7/01/2013
ver 1.0.42

^ Back to Top

MolDX Home / Non-Covered Tests
MolDX
Non-Covered Tests

Last updated date 09/01/2013:
OncoCee is no longer on the list. Its status is unknown.

The following test types are not considered a Medicare benefit and therefore will be denied coverage:

- Tests considered screening (e.g., germ line testing in the absence of clinical signs and symptoms of disease), except for screening tests explicitly identified as covered in the Social Security Act)
- Tests that do not provide the clinician with actionable data (i.e., information that will improve patient outcomes and/or change patient management)
- Tests that confirm a diagnosis or other known information (where confirmation is not reasonable and necessary)
- Tests that determine the risk of developing a disease or condition in the absence or signs or symptoms of such condition or pre-cursor condition
- Tests without diagnosis-specific indication(s)
- Tests performed to measure the quality of a process
- Tests for quality control or quality assurance (e.g., tests performed to ensure that a specimen matches the patient)

Page 1 of 125 | 50 | 100 Per Page

MolDX: BLM Gene Analysis Coding and Billing Guidelines	07/30/2013
MolDX: GBA Genetic Testing Coding and Billing Guidelines	07/30/2013
MolDX: myPap Billing and Coding Guidelines	07/25/2013
MolDX: ATP7B Gene Tests Coding and Billing Guidelines	07/24/2013
MolDX: know error Coding and Billing Guidelines	07/24/2013
MolDX: CYP2B6 Test Coding and Billing Guidelines	07/10/2013
MolDX: MMACHC Test Coding and Billing Guidelines	07/10/2013
MolDX: VEGFR2 Tests Coding and Billing Guidelines	07/10/2013
MolDX: PIK3CA Gene Tests Coding and Billing Guidelines	06/28/2013
MolDX: STAT3 Gene Testing Coding and Billing Guidelines	06/26/2013
MolDX: CHD7 Gene Analysis Coding and Billing Guidelines	06/25/2013
MolDX: HTTLPR Gene Testing Coding and Billing Guidelines	06/25/2013
MolDX: MPL Gene Tests Coding and Billing Guidelines	06/25/2013
MolDX: NSD1 Gene Tests Coding and Billing Guidelines	06/25/2013
MolDX: RPS19 Gene Tests Coding and Billing Guidelines	06/25/2013
MolDX: TERC Gene Tests Coding and Billing Guidelines	06/25/2013
MolDX: HBB Full Gene Sequencing Coding and Billing Guidelines	06/24/2013
MolDX: TP53 Gene Test Coding and Billing Guidelines	06/24/2013
Specimen Validity Testing	06/20/2013
MolDX: UGT1A1 Gene Analysis Coding and Billing Guidelines	02/27/2013
MolDX: MECP2 Genetic Testing Coding and Billing Guidelines	02/19/2013
MolDX: Arrhythmogenic Right Ventricular Dysplasia/Cardiomyopathy (ARVD/C) Testing Coding and Billing Guidelines	02/07/2013
MolDX: Aspartoacyclase 2 Deficiency Testing Coding and Billing Guidelines	02/07/2013
MolDX: BCKDHB Gene Test Coding and Billing Guidelines	02/07/2013
MolDX: HEXA Gene Analysis Coding and Billing Guidelines	02/07/2013
MolDX: IKBKAP Genetic Testing Coding and Billing Guidelines	02/07/2013
MolDX: SMPD1 Genetic Testing Coding and Billing Guidelines	02/07/2013
MolDX: FANCC Genetic Testing Coding and Billing Guidelines	02/06/2013
MolDX: HAX1 Gene Sequencing Coding and Billing Guidelines	02/06/2013
MolDX: MCOLN1 Genetic Testing Coding and Billing Guidelines	02/06/2013
MolDX: CFTR Gene Analysis Coding and Billing Guidelines	02/05/2013
MolDX: Fragile X Coding and Billing Guidelines	01/31/2013
MolDX: L1CAM Gene Sequencing Coding and Billing Guidelines	01/29/2013
MolDX: Mitochondrial Nuclear Gene Tests Coding and Billing Guidelines	01/29/2013
MolDX: PAX6 Gene Sequencing Coding and Billing Guidelines	01/29/2013
MolDX: 4q25-AF Risk Genotype Coding and Billing Guidelines	01/07/2013
MolDX: 9p21 Genotype Test Coding and Billing Guidelines	01/07/2013

MolDX: ApoE Genotype Coding and Billing Guidelines	01/07/2013
MolDX: BluePrint Coding and Billing Guidelines	01/07/2013
MolDX: KIF6 Genotype Coding and Billing Guidelines	01/07/2013
MolDX: LPA-Aspirin Genotype Coding and Billing Guidelines	01/07/2013
MolDX: LPA-Intron 25 Genotype Coding and Billing Guidelines	01/07/2013
MolDX: Pervenio Lung RS Assay Coding and Billing Guidelines	01/07/2013
MolDX: PreDx Coding and Billing Guidelines	01/07/2013
MolDX: Prostate Molecular Markers Coding and Billing Guidelines	01/07/2013
MolDX: SLCO1B1 Genotype Coding and Billing Guidelines	01/07/2013
MolDX: Cytogenomic Constitutional Microarray Analysis Coding and Billing Guidelines	01/02/2013
MolDX: Septin 9 Methylated DNA Test Coding and Billing Guidelines	12/21/2012

25 | 50 | 100 Per Page

last updated on 9/01/2013

ver 1.0.0

^ Back to Top

PTCH1 - page has been updated/changed.
Note dates for Onco DX tests

MolDX Home / Covered Tests
MolDX
Covered Tests

MolDX reviews test registration applications and technical assessments (TA) to confirm that each test meets Medicare reasonable and necessary criteria. Covered tests reviewed through the TA process are identified in the Molecular Diagnostic Test policy found in the LCD section. Coding and Billing guidelines are available to facilitate reimbursement.

MolDX: PTCH1 Gene Testing Coding and Billing Guidelines	07/10/2013
MolDX: Vectra DA Coding and Billing Guidelines	07/02/2013
MolDX: BCR-ABL Coding and Billing Guidelines Update	06/19/2013
MolDX: CYP2C9 and/or VKORC1 Gene Testing for Warfarin Response Coding and Billing Guidelines	06/05/2013
MolDX: Oncotype DX Breast Cancer Assay Coding and Billing Guidelines	05/08/2013
MolDX: therascreen KRAS PCR Kit Billing/Coding Guidelines	04/29/2013
MolDX: CellSearch Coding and Billing Guidelines	03/19/2013
MolDX: bioTheranostics Cancer TYPE ID Coding and Billing Guidelines	02/21/2013
MolDX: Vysis Kit by Abbott Coding and Billing Guidelines	12/12/2012
MolDX: Progensa PCA3 Assay Coding and Billing Guidelines	09/11/2012
MolDX: cobas 4800 BRAF V600 Test Coding and Billing Guidelines	09/07/2012
MolDX: Corus CAD Test Coding and Billing Guidelines	08/07/2012
MolDX: Oncotype DX Colon Cancer Assay Coding and Billing Guidelines	06/28/2012
MolDX: Avise PG Assay Coding and Billing Guidelines	05/24/2012
MolDX: Pathwork Tissue of Origin Test Coding and Billing Guidelines	04/26/2012
MolDX: HERmark Assay by Monogram Coding and Billing Guidelines	04/23/2012
MolDX: MammaPrint Billing and Coding Guidelines Update	03/12/2012
MolDX: AlloMap Coding and Billing Guidelines	03/07/2012
MolDX: Afirma Assay by Veracyte Coding and Billing Guidelines	03/05/2012

last updated on 9/01/2013

ver 1.0.0

^ Back to Top

Oncotype DX tests - pages have been changed/updated since last page capture on 09/10/2013

MolDX Home / Covered Tests
MolDX
Covered Tests

MolDX reviews test registration applications and technical assessments (TA) to confirm that each test meets Medicare reasonable and necessary criteria. Covered tests reviewed through the TA process are identified in the Molecular Diagnostic Test policy found in the LCD section. Coding and Billing guidelines are available to facilitate reimbursement.

MolDX: Oncotype DX Breast Cancer Assay Coding and Billing Guidelines New!	09/23/2013
Chimerism Testing Billing and Coding Guidelines	09/19/2013
MolDX: Oncotype DX Colon Cancer Assay Coding and Billing Guidelines	09/19/2013
MolDX: Approved Gene Testing	09/17/2013
MolDX: cobas EGFR Mutation Test Coding and Billing Guidelines	09/12/2013
MolDX: therascreen EGFR RGQ PCR Kit Coding and Billing Guidelines	09/12/2013
MolDX: PTCH1 Gene Testing Coding and Billing Guidelines	07/10/2013
MolDX: Vectra DA Coding and Billing Guidelines	07/02/2013
MolDX: BCR-ABL Coding and Billing Guidelines Update	06/19/2013
MolDX: CYP2C9 and/or VKORC1 Gene Testing for Warfarin Response Coding and Billing Guidelines	06/05/2013
MolDX: therascreen KRAS PCR Kit Billing/Coding Guidelines	04/29/2013
MolDX: CellSearch Coding and Billing Guidelines	03/19/2013
MolDX: bioTheranostics Cancer TYPE ID Coding and Billing Guidelines	02/21/2013
MolDX: Vysis Kit by Abbott Coding and Billing Guidelines	12/12/2012
MolDX: Progensa PCA3 Assay Coding and Billing Guidelines	09/11/2012
MolDX: cobas 4800 BRAF V600 Test Coding and Billing Guidelines	09/07/2012
MolDX: Corus CAD Test Coding and Billing Guidelines	08/07/2012
MolDX: Avise PG Assay Coding and Billing Guidelines	05/24/2012
MolDX: Pathwork Tissue of Origin Test Coding and Billing Guidelines	04/26/2012
MolDX: HERmark Assay by Monogram Coding and Billing Guidelines	04/23/2012
MolDX: MammaPrint Billing and Coding Guidelines Update	03/12/2012
MolDX: AlloMap Coding and Billing Guidelines	03/07/2012
MolDX: Afirma Assay by Veracyte Coding and Billing Guidelines	03/05/2012

last updated on 9/01/2013

ver 1.0.0

^ Back to Top

Oncotype DX Breast - page has been updated/changed since last capture on 09/29/3013

MolDX Home / Covered Tests
MolDX
Covered Tests

MolDX reviews test registration applications and technical assessments (TA) to confirm that each test meets Medicare reasonable and necessary criteria. Covered tests reviewed through the TA process are identified in the Molecular Diagnostic Test policy found in the LCD section. Coding and Billing guidelines are available to facilitate reimbursement.

MolDX: Oncotype DX Breast Cancer Assay Coding and Billing Guidelines New!	10/10/2013
Chimerism Testing Billing and Coding Guidelines	09/19/2013
MolDX: Oncotype DX Colon Cancer Assay Coding and Billing Guidelines	09/19/2013
MolDX: Approved Gene Testing	09/17/2013
MolDX: cobas EGFR Mutation Test Coding and Billing Guidelines	09/12/2013
MolDX: therascreen EGFR RGQ PCR Kit Coding and Billing Guidelines	09/12/2013
MolDX: PTCH1 Gene Testing Coding and Billing Guidelines	07/10/2013
MolDX: Vectra DA Coding and Billing Guidelines	07/02/2013
MolDX: BCR-ABL Coding and Billing Guidelines Update	06/19/2013
MolDX: CYP2C9 and/or VKORC1 Gene Testing for Warfarin Response Coding and Billing Guidelines	06/05/2013
MolDX: therascreen KRAS PCR Kit Billing/Coding Guidelines	04/29/2013
MolDX: CellSearch Coding and Billing Guidelines	03/19/2013
MolDX: bioTheranostics Cancer TYPE ID Coding and Billing Guidelines	02/21/2013
MolDX: Vysis Kit by Abbott Coding and Billing Guidelines	12/12/2012
MolDX: Progensa PCA3 Assay Coding and Billing Guidelines	09/11/2012
MolDX: cobas 4800 BRAF V600 Test Coding and Billing Guidelines	09/07/2012
MolDX: Corus CAD Test Coding and Billing Guidelines	08/07/2012
MolDX: Avise PG Assay Coding and Billing Guidelines	05/24/2012
MolDX: Pathwork Tissue of Origin Test Coding and Billing Guidelines	04/26/2012
MolDX: HERmark Assay by Monogram Coding and Billing Guidelines	04/23/2012
MolDX: MammaPrint Billing and Coding Guidelines Update	03/12/2012
MolDX: AlloMap Coding and Billing Guidelines	03/07/2012
MolDX: Afirma Assay by Veracyte Coding and Billing Guidelines	03/05/2012

last updated on 10/01/2013

ver 1.0.0

^ Back to Top

MolDX Home / Covered Tests / MolDx: Oncotype DX Breast Cancer Assay Coding and Billing Guidelines
MolDX
MolDX: Oncotype DX Breast Cancer Assay Coding and Billing Guidelines

Oncotype DX® Breast was developed for patients with the following findings:

- estrogen-receptor positive, node-negative carcinoma of the breast
- estrogen-receptor positive micrometastases of carcinoma of the breast, and
- estrogen-receptor positive breast carcinoma with 1-3 positive nodes

To bill an Oncotype Breast service, please provide the following claim information:

- CPT code 84999 – Unlisted Chemistry Procedure
- Enter '1' in the Days/Unit field
- Select the appropriate ICD-9-CM code:
  - 174.0-174.8 – Malignant neoplasm of nipple and areola of female breast – Malignant neoplasm of other specified sites of female breast,
  - 174.9 – Malignant neoplasm of Breast (Female) unspecified site,
  - 175.0 - Malignant Neoplasm of Nipple and areola of Male Breast,
  - 175.9 – Malignant Neoplasm of other and unspecified sites of male breast,
  - 233.0 – Carcinoma in situ of breast
  - V86.0 – Estrogen Receptor Positive status [ER+]
- Enter 'ZBI65' in the comment/narrative field for the following claim field/types:
  - Loop 2400, NTE02, or SV101-7 for the 5010A1 837P
  - Submit 'ZBI65' on an attachment to the claim form for paper claim

last updated on 10/10/2013

ver 1.0.0

The published LCDs indicate there is a publication of coverage on 10/31/2012 which has not yet been located.
Article - A51727/A51726 were posted 3/20/2012.
Web page was first posted 05/08/2013.
Dates of updates to web page:
--09/23/2013
--10/10/2013.
No tracking or indication of what has been changed each time.

Attachment F: Concerns and Inconsistencies with web page statements

We have a number of concerns about the webpage statements which need to be addressed.

I. Multiple, inconsistent effective dates

There are multiple statements of coverage and non-coverage with different effective dates. It is not clear what the effective dates should be except that if it is the LCD which defines the Program and it is the only LCD, then the effective dates for the covered and non-covered services should be based on the effective dates of the published LCDs*.

If the date of the Program application for the Jurisdiction is the effective date of the LCD, then it is not clear how the webpage statements with dates in the past will be applied to claims processing and auditing. For J11, all the items on the "non-covered test" list were posted on the website with effective dates before the effective date of LCD 33599. There are 5 statements on the covered list addressing over 130 procedures that were not included in the LCD for J 11 and 4 that are not included in LCD 33541 for JE, effective 09/16/2013.

The LCD instructions from Medicare are that new coverage decisions are not be retroactive [PIM 83 §13.7.4]. The Notice Period requires the effective date be 45 days in the future. Analysis of the web page statements for 49 Non-Covered Tests and 21 on the Covered Tests List has identified multiple instances of retroactive effective dates for these unofficial local decisions about coverage.

Effective date of the local coverage decision	Covered Tests	Non-covered Tests
Retroactive date	11	3
Same date as Article/web page posting	5	28
No date listed	3	18
Not clear	2	0

- For those statements for which there is no indication of the effective date, it is not clear whether Palmetto will consider the statement to be effective for the dates of service or for the date the claim is filed.
    - The instructions state that during the TA review period, claims submission "*should be suspended in order to avoid denials."* [Technical Assessment (TA) Process-dated 08/23/2013]
    - The FAQ Billing and Coding sections states that Z-Code Identifiers are effective at time of assignment.
    - Another statement reads that the date of publication of the decision is the effective date for the UI but each statement is an announcement of the UI and the coverage decision.
    - It is not clear if Palmetto will change past payment based on the new TA:

      "*Prior to the TA, claims will process according to the billed services. If information in the TA indicates a noncovered service or inappropriate billing, Palmetto GBA will make the appropriate corrections*." [FAQ/Reimbursement/Question#5. Posted 10/3/2013]

See Attachment C: Table of Procedures, Support Documents and Effective Dates for details.

SUMMARY:

It is impossible for a clinical lab and physician ordering tests to accurately inform the beneficiary about whether the procedure will be covered by Medicare or not. It is impossible to discern what will be covered or not covered by the effective dates.

*Published LCDs: L33541, L33599 and L32288 (for services prior to 09/16/2013 in JE)

- Beneficiaries and providers should be able to use effective dates that are consistent with the effective date of the LCD for each jurisdiction.
- Beneficiaries and providers should not be held to effective dates in webpage statements especially those in the past before the LCD was in effect.
- When these webpage statements are developed as LCDs, effective dates be assigned consistent with Medicare instructions, specifically, no retroactive dates for new coverage or for non-coverage decisions.

II. Policies regarding 'panels' of tests created by Palmetto

A. Denial of an entire 'panel' of tests when 1 of the components is not covered

EXAMPLE:
PIK3CA – Colorectal Cancer

Test	Identifier	CPT code Assigned in webpage	Current specific CPT codes for tests listed in panel
Colorectal Cancer Mutation Panel (KRAS, PIK3CA, BRAF, NRAS)	PBD71	81479	KRAS-81275, 81403,81405; BRAF-81210, 81406; NRAS-81404

This test of multiple genes will be denied because PIK3CA is not covered. In this example, the Program has listed KRAS, BRAF and NRAS as covered tests. Only PIK3CA has been determined to be not covered. The lab should be allowed to bill the analyte-specific individual CPT codes for the tests performed. Then, only PIK3CA should be denied; the other 3 tests should be paid assuming the individual meets 'reasonable and necessary' criteria.

For molecular pathology, a 'panel' of tests does not usually refer to a panel that has been defined by a CPT code. There are only a few CPT codes for molecular pathology that would be considered a 'panel' that includes a number of specific genes. CPT code 81280 is one example of a CPT-defined panel: the descriptor is "Long QT - gene analyses (eg, KCNQ1, KCNH2, SCN5A, KCNE1, KCNE2, KCNJ2, CACNA1C, CAV3, SCN4B, AKAP, SNTA1, and ANK2)'. This is not the type of 'panel' the Program is addressing. As in the PIK3A, the 'panel' being referred to by the Program is multiple tests where each might have a unique, gene/analyte specific CPT code.

The grouping of related tests for a clinical condition into a single 'panel' on a lab ordering form can be done to facilitate ordering by the physician. The 'grouping' makes it simpler for the physician to order all the relevant tests without going through a long list of tests and they make the lab ordering form less cumbersome. There is no prohibition on creating these 'panels' of tests as long as each is medically reasonable and necessary for the condition and the ordering physician understands what tests are included in the grouping.

Regardless of how they are ordered, the individual tests would be performed and a report generated for each test. They would be billed individually, using their appropriate CPT code and associated diagnosis codes. Whether they are paid or not depends solely on the coverage status of each test. If any of the tests are not covered, that is the only test that should be denied.

*Published LCDs: L33541, L33599 and L32288 (for services prior to 09/16/2013 in JE)

In general, when more than 1 service is provided on the same day and some are covered while others are not, the services are entered separately on the claim form and then each is adjudicated individually. We have found support for this conclusion in the following:

1) Instructions on how to review a covered office visit at the same time as a noncovered preventive service provides support for this position.

   "There could be covered and noncovered procedures performed during this encounter (e.g., screening x-ray, EKG, lab tests.). These are considered individually. Those procedures which are for screening for asymptomatic conditions are considered noncovered and, therefore, no payment is made. Those procedures ordered to diagnose or monitor a symptom, medical condition, or treatment are evaluated for medical necessity and, if covered, are paid." [Source CLM 104 Ch12 §30.6.2]

2) Medicare's position on this is addressed in the section of the manual on Laboratory Services (CLM104, Chapter 16), addressing automated tests. The automated tests have different issues because they are performed using an automated machine and have unique payment issues associated with them that do not apply to molecular pathology tests, however, for chemistry tests performed in a profile, 'payment is made only for those tests in the profile that meet Medicare coverage". [§16.90.1.1]. It goes on to describe how payment should be made when the 12-channel test is used 'where only some of the tests in the profile of tests are covered.'

3) In the section on Organ or Disease Oriented Panels, there are instructions for processing claims for the CPT codes for the Organ and Disease Oriented laboratory panels. Contractors are advised that if they do suspect abuse of the codes and see a need to develop an LCD for the laboratory panel codes, they are to develop the policy at the panel code level. Even when there are codes that include a combination of tests, the handling of 'problem' tests is to be done on the individual test level. "In some instances of perceived abuse of the panel codes, the contractors may review the panel and deny component tests on a case-by-case basis or evaluate the need for the component level test." (PIM 83 §3.4.1.3 C. Requirements for Lab Claims).

REQUEST:

- Revise Palmetto's statement and adjudication of claims to reflect Medicare's position: that even if ordered as a group (profile or panel, molecular pathology tests will be covered based on the coverage status of each component test. Only individual tests for which there is an LCD statement that the specific test is not covered or, in the absence of an associated LCD, an individual manual medical review of the test for reasonable and necessary criteria for that individual will be denied, with the appropriate indication of the reason for the denial and associated LCD.

- Instruct laboratories of the change and request that claims for tests performed the same day that have been denied as a panel where one of the tests was not covered.

- Because re-opening claims is at the MACs discretion, we ask that Palmetto reopen claims and adjudicate each test based on the coverage status of each component test.

*Published LCDs: L33541, L33599 and L32288 (for services prior to 09/16/2013 in JE)

Attachment F: Concerns and Inconsistencies with web page statements

III. Requiring that the providers use the procedure developers indications for a procedure

In the published LCDs*, the only statement for clinical criteria for test indications is the following:

FL33599 and L32288 read "Palmetto GBA expects laboratory providers to follow test indications published by the developer."

L33541 reads: "Both Noridian and Palmetto GBA expect laboratory providers to follow test indications published by the developer."

This requirement raises many serious concerns.

- Most concerning is the fact that by making this statement, the MolDX Program has delegated their responsibility for determining what meets 'reasonable and necessary" criteria for this test to an outside entity which has no accountability or authority to make these decisions for coverage and payment of services by Medicare nor is it bound by the statute and Medicare's criteria to determine 'reasonable and necessary' in its selection of indications.

- We do not believe a physician/laboratory can be held accountable to such a vague requirement.

- It does not provide sufficient information about what the MolDX Program considers to be covered indications that meet 'reasonable and necessary' criteria. It does not fulfill the requirements of an LCD and does not provide the level of detail about the test and the diagnosis or indications that would constitute 'clear policy' that would be needed to create an automated review/edit for these tests.
  - The LCD is to be "*clear and concise"*.
  - It is to describe in the draft LCD the circumstances under which the item or service is reasonable and necessary under 1862(a)(1)(A). [PIM 83 §13.5.1].
  - This includes identifying '*Only codes describing what is covered and what is not covered can be part of the LCD. This includes, for example, lists of HCPCs codes that spell out which items or services the LCD applies to, lists of ICD-9 codes for which the item or service is covered, lists of ICD-9 codes for which the item or service is not considered reasonable and necessary, etc*. " [PIM 83 §13.5.2]

- It is counter to all Medicare instructions to MACS about the development of LCDs and with all activities related to national coverage decisions to require the use of the developer's indications as the sole factor for coverage determination.

- The developer's indications for a test could be one element considered in making a decision about coverage criteria. The MAC is required to look to the scientific evidence in its coverage determination which includes indications for the service/procedure. The indications should first be based on the published authoritative evidence, scientific data in peer-reviewed medical journals, consensus of expert medical opinion as presented in clinical practice guidelines and medical evidence as presented in the literature, the clinical practice guidelines and technology assessments. Second, they should be based on the recommendations of the medical community and consistent with the evidence. The developer's recommended indications should not be taken at face value without going through the LCD process to allow for review and comment by the medical community as to the use of the test in medical practice.

*Published LCDs: L33541, L33599 and L32288 (for services prior to 09/16/2013 in JE)

- The developer of a test which is FDA-approved is limited to the indications approved by the FDA. However, the scientific literature could provide sufficient evidence to support coverage for other indications which would apply to the LDTs and be an 'off-label' indication for the FDA-approved test.

- The developer's statement of the indications for the test as found in their brochure or website is not 'clear policy' as defined by Medicare. It would be inappropriate for the Program to create an automatic edit for these tests based on this statement or to use the developer's criteria for manual review or redeterminations. The ICD-9 or other criteria (e.g. frequency) it might use to identify the condition for which the test is covered (ICD-9) are not stated in the LCD. They are unknown to the physician, laboratory, and beneficiary.

- There are practical, claims adjudication issues as well as post-pay review problems.
  - The developer is free to change their list of indications as they chose with no notice or external review and without evidence to support the change.
  - There is no obligation that the developer communicates with the Medicare community (providers, beneficiaries or MAC) what their criteria are or when they make changes. Their criteria are not entered into the MCD as an LCD or Article. They are not even posted on the MolDX website for most tests.
  - There is no tracking system that would allow one to determine what indications were in place at the time a service was provided, in order to determine if the service has been provided according to the developer's indications. This has implications from a claims processing and audit perspective. There is no way a provider/lab can prove that they were consistent or Medicare can prove that they were not consistent at the time the service was provided.
  - The recommendations of the developer could be interpreted differently by the medical community and the MAC.

IV. Instructions to present additional medical information to obtain an individual coverage decision on appeal for a procedure that has been declared to be a 'statutory exclusion'.

It is our understanding that services/tests declared to be statutory exclusions cannot be overridden on appeal. Other manual instructions indicate that if a service is determined to be excluded based on the statute, it is never paid unless the statute describes the exception or there is a separate statute that allows coverage.

Screening services that are not paid under the statutory exclusion are not covered under any circumstance. [65 FR p 13086, column 2] Whether the service is medically indicated for the individual person is irrelevant: the statutory exclusion takes precedence over 'reasonable and necessary' decision. [PIM 83 §3.6.2.5.A – Example 2] Therefore, a different coverage decision could not be made on appeal regardless of the documentation that the individual met 'reasonable and necessary' criteria.

EXAMPLES– excerpts from website statements for tests declared to be statutory exclusions:

LPA-Aspirin Genotype:

"*EXCEPTIONS: For patients with 'suspected' HHT in which diagnosis confirmation would demonstrate an improved outcome, approval will be made on a case-by-case basis through the appeal process*."

ENG/ACVRL1:

*Published LCDs: L33541, L33599 and L32288 (for services prior to 09/16/2013 in JE)

"*The two most prevalent forms of HHT, Type 1 and Type 2, are caused by mutations in the endoglin (ENG) or the ACVRL1 gene respectively. Although identification of these gene mutations can confirm the diagnosis of HHT, these tests are not necessary in many cases. HHT is generally established using well vetted consensus criteria (most often the International Curaçao Criteria (ICC)). The ICC uses the clinical characteristics of epistaxis, cutaneous or mucosal telangectasias, visceral AVMs, and a first-degree relative with HHT to judge likelihood of a given patient having HHT. A 'definite' diagnosis is established when a patient has three or four of these criteria. Genetic testing for ENG/ACVRL1 is not warranted. A patient with zero to one criteria is 'unlikely' to have HHT, and similarly would not be a candidate for genetic testing. Patients with two or three Curaçao criteria are defined as 'suspected' of HHT and are candidates for ENG/ACVRL1 testing.*

Since screening of patients without signs or symptoms of HHT, who have a first-degree relative with HHT, is not a Medicare benefit, Palmetto GBA has determined ENG and/or ACVRL1 genetic testing and panels of tests that include ENG/ACVRL1 are statutorily excluded services.

EXCEPTIONS: For patients with 'suspected' HHT in which diagnosis confirmation would demonstrate an improved outcome, approval will be made on a case-by-case basis through the appeal process."

First, it appears the intention is to not cover use of the tests for screening the asymptomatic patients which is a statutory exclusion. This can be accomplished with instructions to use the ICD-9 code 'V82.7 Screening for genetic disease carrier status' or 'V83.89 Other genetic carrier status' to indicate testing was done in the asymptomatic beneficiary and will be denied as a statutory exclusion.

If the MAC wants to recognize and cover the exceptions cited, an LCD could be created that states these are the criteria for coverage. The LCD could request that one of the existing modifiers be applied to the CPT code to indicate that the patient meets these criteria:

Modifier	Long Description	Short Description
CG	Policy criteria applied	Policy Criteria Applied
KX	Requirements specified in the medical policy have been met	Documents on file

Claims which do NOT have the identifier would be denied as not meeting 'reasonable and necessary' criteria. Those for whom the test meets the MolDX Program's criteria published in an LCD could and would be covered without additional claims submission or processing by the lab, the physician, the patient or the MAC. By applying the modifier, they are indicating they are aware of the LCD and coverage limitations. Post-payment review could be performed with review of the documentation if there are questions of misuse of the modifier.

V. Listing the "CPT code-GA" to report the service:

Some of the webpage instructions require that the CPT code to be used be reported as "CPT Code 83891–GA".

*Published LCDs: L33541, L33599 and L32288 (for services prior to 09/16/2013 in JE)

EXAMPLES:

Gene/analyte specific tests which require the use of the CPT codes in Column 2	CPT Code instruction: they are required to use these codes to report the service
LPA-Aspirin Genotype	83891-GA
LPA-Intron 25	83896-GA
4q25-AF	83898-GA
9p21 genotype	83903-GA
SLCO1B1	83912-GA

It is easy to assume that the –GA attached to the CPT code has a different meaning for the MolDX program, however, the –GA attached to a CPT code is a modifier that is intended to communicate the following to the payer: "waiver of liability statement issued as required by payer policy, individual case." This is not explained in the web statement instructing the use of these codes with the -GA attached.

Reporting the test as instructed with –GA has the lab making a statement on the claim that may not in fact be true. They may not have obtained a waiver of liability statement. They may not realize they are submitting the CPT with a recognized modifier, GA.

There is further confusion because the web statements go on to instruct providers to use either the –GX or –GY modifier with the claim submission:

"*An Advance Beneficiary Notice (ABN) is not required for statutorily excluded services.*

- *For a voluntary issued ABN, append with GX HCPCS modifier*
- *To indicate a valid ABN is on file for a known statutorily excluded service, append with a GY modifier*"

VI. Inconsistent information about the use of modifiers

EXAMPLE: Prostate Molecular Markers

There are 3 genes addressed in this web statement: PTEN, ERG, and HOXD3. All of them are declared to be statutorily excluded services, however, the instructions on application of modifiers is not the same for all the genes/tests.

- PTEN and ERG: they are instructed to "*append the modifier GA to indicate a valid Advance Beneficiary Notice (ABN) is on file for the service*."
- HOXD3 – the instructions are: "*An Advance Beneficiary Notice (ABN) is not required for statutorily excluded services*
  - *For a voluntary issued ABN, append with GX modifier*
  - *To indicate a statutorily excluded service, append with a GY modifier"*

VII. Need for clear information about the reason for denial that will be used for tests prior to obtaining a unique identifier as well as instructions on how claims will be processed once an identifier is obtained.

FAQ:

"5. If the lab submits a MolDX covered test without a unique identifier after the implementation date, will Palmetto GBA reject the claim as 'unprocessable' with no appeal rights or send a denial with a specific or new claim denial message?

Claims received without additional information required to adjudicate the claim will be rejected."

*Published LCDs: L33541, L33599 and L32288 (for services prior to 09/16/2013 in JE)

Given the size of this Program and the reality that large volumes of claims are being denied as non-covered because the lab has not yet requested or been given a unique identifier or they are incorrectly listed as statutory exclusions, it is important that Palmetto give clear instructions about the status of claims denied and how the laboratory is to proceed.

Providers/labs cannot assume that they will be able to resubmit the claim or that their request that Palmetto reopen the claim will be honored. Reopening a claim is not a given or a right of the provider/lab. Re-opening claims is done at the discretion of the MAC.

The published LCDs*do not contain information that addresses this question. If these questions are not addressed in the LCD, there is often an Article which provides additional information about billing and coding. However, there are no associated documents cited with the LCD/FLCD. There are no Articles entered into the MCD that provide the guidance needed.

While information contained on the website is helpful, it does not constitute official instructions to guide claims submission unless it is presented as an LCD or Article and entered into the MCD.

REQUEST:
Please provide appropriate billing and coding guidance as an Article that is entered into the MCD about how claims that have been denied as non-covered under the LCDs and how Palmetto plans to manage them.

VIII. Use of the CED process at the MAC level

We have not been able to identify language or instructions from CMS that extend the authority of the contractors to develop LCDs using a local CED process to cover investigational or experimental services/items within their jurisdiction. We question the authority of Palmetto or any MAC to cover 'promising but unproven diagnostic tests' under any process.

Specifically, the MolDX website states the following: **MolDX Coverage with Evidence Development**

> *During a review of the clinical utility component of a MolDX Technical Assessment (TA), Palmetto GBA recognized the need to develop a mechanism to provide rapid patient access, while also generating the evidence necessary to assess benefits and risks for test(s)/service(s) that meet the following criteria:*
>
> - *Demonstrates strong evidence of clinical validity*
> - *Demonstrates strong evidence of analytical validity*
> - *Demonstrates potentially significant, but unproven potential of clinical utility*
> - *Demonstrates the potential to affect the management of a serious, prevalent disease within the Medicare population*
>
> *Under this approved mechanism, also known as a Coverage with Evidence Development (CED), the MolDX Program may provide coverage for promising, but unproven diagnostic tests contingent on the submission of plans to conduct a clinical study that will generate additional evidence to support their safety, diagnostic performance, and most importantly, clinical utility.*

- We are aware that Medicare has the authority and uses the CED process in conjunction with the National Coverage Determination process, which is described in the Draft Guidance for the Public,

*Published LCDs: L33541, L33599 and L32288 (for services prior to 09/16/2013 in JE)

Industry and CMS Staff Coverage with Evidence Development, dated 11/29/2012. It states that CMS bases the authority based on §1862(a)(1)(E), which refers to section 1142. Section 1142 describes the authority of AHRQ to conduct studies.

- If the authority has been extended, then we look to CMS to provide guidance on how the MACs should implement the authority, using the NCD with Data Collection: CED as a template. This should not be left up to each MAC as to how it will exercise this authority. The process by which the MACs will implement this should be developed at the national level with public input. We would expect the same safeguards and provisions associated with the national use of the CED would be applied to the MAC application and that the MAC application would not be more restrictive or proscriptive than the application of the NCD with Data Collection: CED. We would also expect that the process be defined first by an LCD that has been developed through the LCD process, just as the NCD is the foundation at the national level.

REQUEST:

- The MolDX Program should refrain from pursing its Coverage with Evidence Development Process until the authority has been confirmed and the requirements for the process as applied at the local level are defined by CMS, through a transparent process that allows public comment, similar that used for NCD with CED.

- IF CMS intends to have the MACs use the CED process, then we expect that it apply to all services and not just molecular pathology tests and that it be made public that it is allowing MACs to use the CED process. We would ask that CMS provide national guidance about how the CED process would be applied at the MAC level, beginning with the requirement that an LCD be developed to provide the framework, similar to the NCD at the national level, that it include safeguards for the patient and that it limit interference in the development of the clinical study (e.g. specifying the qualifications of who can help design and implement a CED).

- If Palmetto has the authority to implement a CED process, we would expect
  - The process and requirements by which the CED is developed would use the national requirements at a minimum and not exceed the national requirements.
  - The process would be presented for public input including the medical community and public prior to its implementation
  - Each individual CED be developed through a process that parallels the national process; it should begin with the LCD process with the publication of a Draft LCD.

*Published LCDs: L33541, L33599 and L32288 (for services prior to 09/16/2013 in JE)

Attachment G: Code Assignment and Identifiers

Creating and assigning new identifiers for molecular procedures that are already identified correctly by CPT in the Molecular Pathology Tier 1 and MAAA codes is causing unintended consequences in reporting services to payers through the automated system and in determining the fee schedule appropriately. It causes confusion and creates a more complicated, separate coding system that is managed by Palmetto, the details of which are known only to McKesson and Palmetto, in essence a private coding and reimbursement system. It will render the Medicare database useless to analyze tests for use and frequency indications unless one has access to the McKesson UI database and if that database includes a listing of each of the specific analytes included in the NOC codes. Payment data for tests that have been diverted into an NOC code will not be available for setting reimbursement levels.

These examples cited here redefine how and when specific CPT codes should be used and when an NOC should be assigned. A review of the webpage statements and assigned codes shows that labs were instructed to use an NOC 67 times. Two of the uses were for specific analytes which will have a Tier 2 in 2014, 4 are for analytes not addressed in Tier 2, and 15 are for MAA type tests or unique tests. The remaining 46 are for analytes with specific CPT codes or for panels created by Palmetto.

1. ***Use of NOC codes to report combinations of tests for which there are currently specific CPT codes.***

NSD1

The instructions on the webpage are:
"…select the appropriate CPT code according to the tests:

- CPT code 81405 for NSD1 duplication/deletion
- CPT code 81406 for NSD1 gene sequencing
- CPT code 81479 for combinations of NSD1 analysis"

Test	Identifier	CPT code
NSD1 Gene Sequencing and Deletion/Duplication	ZBS65	81479

The laboratory should be required to submit the specific CPT code for the tests performed. It there is a question of the medical appropriateness of the tests being performed, that should be addressed through an LCD that addresses the clinical condition, the indications for testing and the specific analytes and their CPT codes. If the issue is the appropriateness of billing the codes together on the same day, if it is not addressed in the CPT instructions, it is an issue for the Correct Coding Initiative to pursue.

BCR-ABL

There are 3 specific CPT codes for BCR-ABL1 testing:

81206: BCR/ABL1 (t(9;22)) (eg, chronic myelogenous leukemia) translocation analysis; major breakpoint, qualitative or quantitative
81207: minor breakpoint, qualitative or quantitative
81208: other breakpoint, qualitative or quantitative.

The webpage statement dated 06/19/2013 identifies 18 lab-test combinations for BCR-ABL which have been assigned an UI and instructed to bill using CPT 81479. It is unknown which of the 3 tests are being performed. The rationale for telling them to bill using the 81479 is that it is common to do testing as "a combination or panel of tests".

The coding does not change for the different the body tissue/fluids on which the test is performed or for the method(s) used to obtain the result.

Attachment G: Code Assignment and Identifiers

	TEST	Identifier	CPT Code
1.	BCR-ABL t(9;22) Quantitative GenoTRACE Assay	PBC68	81479
2.	BCR/ABL, Quantitative, t(9;22) for CML, ALL	PBD35	81479
3.	Qualitative w/ reflex to BCR-ABL1	PBH42	81479
4.	BCR-ABL, t(9;22) Translocation Qualitative by RT-PCR	PBK21	81479
5.	BCR/ABL t(9;22) Quantification	PBK88	81479
6.	BCR/ABL Qualitative PCR	PBL46	81479
7.	BCR/ABL, mRNA Detection, Reverse Transcription-PCR (RT-PCR), Qualitative, Diagnostic Assay	PBM81	81479
8.	BCR/ABL quantitative	ZB884	81479
9.	BCR/ABL qualitative	ZB888	81479
10.	Qualitative BCR-ABL, Blood	ZB970	81479
11.	Qualitative BCR-ABL, Bone Marrow	ZB971	81479
12.	Qualitative BCR-ABL, Tissue	ZB972	81479
13.	Quantitative BCR-ABL, Blood	ZB999	81479
14.	Quantitative BCR-ABL, Bone Marrow	ZBA01	81479
15.	Quantitative BCR-ABL, Fluid	ZBA02	81479
16.	Molecular t(9;22) RT-PCR	ZBA57	81479
17.	BCR/ABL1 ANALYSIS QUANTITATIVE	ZBB35	81479
18.	BCR/ABL1 Major-Minor	ZBK90	81479

BLM - Bloom Syndrome

Test	Identifier	CPT code Assigned in webpage	Current specific CPT codes for analytes listed in panel
Ashkenazi Jewish Diseases (BLM, ASPA, IKBKAP, FANCC, GBA, MCOLN1, SMPD1, HEXA)	PBH00	81479	BLM-81209; ASPA-81200; IKBKAP-81260; FANCC-81242; GBA-81251; MCOLN1-81290; SMPD1-81330; HEXA-81255

All the tests listed in this lab's panel have specific CPT codes. The lab should be allowed to use the specific code for claims submission. If administered without discrimination, a UI should be assigned to each analyte-specific test so that it is used whenever that test is performed, whether it is done alone or in combination with other tests or performed for other indications. This allows for the development of a coverage policy for each gene/test and its indications. Then LCD could then be associated with automatic edits that would be consistent in all circumstances in which the test is performed and billed.

PIK3CA – Colorectal Cancer

Test	Identifier	CPT code Assigned in	Current specific CPT codes for analytes listed in panel

		webpage	
Colorectal Cancer Mutation Panel (KRAS, PIK3CA, BRAF, NRAS)	PBD71	81479	KRAS-81275, 81403,81405; BRAF-81210, 81406; NRAS-81404

All but 1 of the genes included in this panel have at least 1 specific CPT code that should be used to report the test. Only PIK3CA does not have a specific code: it is the only gene/analyte that should be assigned to an NOC code with its own UI. All the other genes/analytes should use the analyte-specific CPT code for claims submission and payment. This allows the payer to make a coverage decision on each of the tests performed and reimbursement would be based on the individual specific CPT code. Because this is not a panel of tests defined by a CPT code, whether the test is ordered or reported in combination with other tests (as a group, panel or profile) is not relevant to the selection of the appropriate CPT code or reimbursement.

---

2. ***Use of the NOC code to report tests or combinations of tests that are not known or understood outside the McKesson system. We are not privy to the list of tests being performed in these instances nor would the details be in the Medicare Claims Database.***

BCR-ABL1 - See details in #1

---

3. **Assigning tests to be billed using a specific CPT code that does not match the description of the test being performed.**

HEXA – Tay - Sachs disease

Test	Identifier	CPT code Assigned in webpage	Current specific CPT codes for analyte
HEXA Mutation Analysis	PBF30	81255	*
Tay-Sachs Disease Mutation Analysis	PBF62	81255	*
Ashkenazi Jewish Panel (4 tests)	PBG41	81255	*
Ashkenazi Jewish Panel-Part A	PBG42	81255	*
Tay-Sachs (HEXA) 7 Mutations	PBH15	81255	81255
Tay-Sachs (HEXA) 7 Mutations, Fetal	PBH16	81255	81255
Tay-Sachs Disease, Mutation Analysis, HEXA	PBN65	81255	*
Tay-Sachs Disease, HEXA Gene, Known Mutation	PBN13	81255	81255
Tay-Sachs Disease, HEXA Gene, Full Gene Analysis	PBN14	81255	81406-HEXA full gene sequence
Tay-Sachs Disease Targeted Mutation Analysis	ZBB68	81255	81255

*Not enough information is provided in the test description to determine whether it has been assigned appropriately or whether the test includes other analyte tests.

It is not clear what the test includes in all cases listed. However, they have all been assigned the same CPT code.

> CPT code 81255 – HEXA (hexosaminidase A [alpha polypeptide]) (eg, Toy-Sachs disease) gene analysis, common variants (eg, 1278insTATC, 1421+1G>C, G269S)

The test with UI PBG41 is clearly described as a 'panel' of 4 tests and PBG42 is also a panel yet they have been assigned to the CPT code to report the single gene test for HEXA.

It would be reasonable to wonder if more than the HEXA gene test is being performed and reported in the tests with UI PBH15, PBH16 yet they are all instructed to bill under 81255.

There is no mention or use of the other CPT code 81406 – HEXA, which would appear to be a more specific and accurate coding for the test with UI PBN14.

---

4. **Assigning an NOC code to an FDA-approved test and the analyte-specific CPT code to the LDT tests for the same gene/analyte-specific test:**
   Coding protocol would require that all tests performed that are consistent with the analyte specific CPT code should be reported using the same CPT code, regardless of the methods used to perform the test. This means FDA-approved tests and LDT tests should be reported under the same CPT code. This is not how the MolDX Program is proceeding.

   EXAMPLE:
   EGFR Mutation Test
   There is a specific CPT code for EGFR:

   > CPT Code 81235: EGFR (epidermal growth factor receptor) (eg, non-small cell lung cancer) gene analysis, common variants (eg, exon 19 LREA deletion, L858R, T790M, G719A, G719S, L861Q)

   Webpage statements:

   - *cobas EFGFR Mutation Test – Last updated 09/12/2013. Effective for service on and after May 14, 2013.*
     Palmetto "*will cover the FDA approved, cobas EGFR Mutation Test for the detection of epidermal growth factor receptor (EGFR) gene for non-small cell lung cancer (NSCLC) tumor tissue*."
     It is to be billed as CPT code 81479 - Unlisted chemistry procedure. The UI is ZBA66.

   - *therascreen EGFR RG PCR Kit – Last updated 09/12/2013. Effective for service on and after 07.12.2013.*
     Palmetto "*will cover the FDA approved, therascreen EGFR RGQ PCR kit for the detection of the epidermal growth factor receptor (EGFR) gene from non-small cell lung cancer (NSCLC) tumor tissue*."
     It is to be billed using the CPT code 81479 – Unlisted chemistry procedure. The UI is ZBZ25.

   - Both webpage statements include the following statement:

     > *"All labs that submit claims for the cobas EGFR kit MUST register the test and confirm the UNMODIFIED use of the kit. For laboratory developed tests (LDT) or*

> *tests that modify the cobas EGFR kit, CPT code 81235 should be reported and submitted with the assigned LDT test ID*."

Requiring that a test not use the specific CPT code that matches the service/test creates problems in tracking tests and code use and is inconsistent with general instructions about selection of the specific CPT code for a service/test when one exists. NOC codes are only to be used when there is no specific code.

It also is being used to create a multi-tiered reimbursement for the FDA-approved test billed as an NOC is much higher than the level assigned to the analyte-specific CPT code.

Rationale for and impact of different coding of the same test
The rationale for this difference in assigning codes is not provided in the web statements. Nonetheless this appears to be an attempt to promote the use of FDA approved assays over laboratory developed tests, a practice at odds with CLIA regulations that allow for the development, validation, and use of test by laboratories under the direction of the laboratory Medical Director. Judgments regarding the relative superiority of analytical methods are beyond the scope of a MAC's authority, as are assessments regarding test efficacy and safety, which are appropriately relegated to FDA and to laboratory Medical Directors.

This notion of creating a separate system using the NOC codes for FDA-approved tests vs. modified FDA-approved tests or LDTs and 'specialty tests' and creating a different payment system is advocated by Palmetto in the following :

- The Claims Submission document, 5.26.2013 (See Attachment E for a copy) includes a column with payment levels, the heading is "PBGA-LDT ONLY".

- In the July 2013 meeting and other meetings at which the Palmetto staff presented, there has been additional discussion of the CPT code gapfill process, which Palmetto staff has commented does not consider 'value'. They described an 'enhanced gapfill' process which is being applied to specialty tests in which they consider cost, costs saved, clinical impact, and pharmacoenconomic value to determine pricing. They want it understood that this approach is not to be confused with the regular CMS gapfill process used for the new CPT codes.

- Statement on the webpage – Molecular Diagnostic Services Program (Last updated 08/23/2013)

> *Reimbursement Determination*
> *Based on the information provided for the TA, Palmetto GBA will apply multiple methodologies appropriate to the specific test to determine an equitable value for each submitted test.*

COMMENT:
This position and practice of assigning the FDA-approved test for a specific gene/analyte an NOC code for billing and require that all other tests (LDTs) use the specific CPT code has very serious implications.

Coding issues

- It is not consistent with the use of a national coding system, in this case the AMA CPT codes, to report services. This system is built on the principle that everyone who provides a service/test is to use the same specific CPT code to report the service. The new codes were carefully designed to make it clear what was being tested, regardless of the methods used by the lab to perform the test and get the results/information cited in the CPT code. The Tier 2 codes were purposely grouped in the different

levels based on the principle that tests listed under one level represented the same level of work/cost. The creation of these codes involved the input of physicians, industry, and payers, including CMS. The practice of separating some of the tests done for a specific gene/analyte and allowing/requiring some to report using an NOC code while others are to use the CPT specific codes creates a multi-tiered, unique Medicare system for reporting and paying for a specific test. In effect, it creates a private coding and reimbursement system that lacks the rigor and transparency of CPT.

Clinical Issues

- If accepted as appropriate, this practice does not recognize the nature of most LDT tests that are modifications of an FDA-approved test and their value to the practice of medicine. It is naïve and unjustified to consider FDA approved assays as superior to laboratory developed tests. Indeed, most FDA approved assays have their origin in LDTs, and it is only when their commercial value becomes apparent that an FDA approved test is developed, if at all. While there may be financial costs associated with assay development and validation in pursuit of FDA approval, such costs are appropriately borne by the developer, recovery of which should not be sought through procedural based reimbursement, i.e. CPT.

- It should also be appreciated that FDA approval of an assay is typically accomplished via clinical trials, frequently linked to a specific pharmaceutical agent. While such clinical trial assays (CTAs) offer a useful benchmark, they are hardly representative of the varied usages of a particular assay with regard to tissues types examined, specimen types processed, or clinical utilization.. It is precisely in these circumstances that modification of FDA approved assays and laboratory developed tests serve to provide needed laboratory services. To discount this important feature of laboratory developed tests fails to appreciate a fundamental facet in the practice of molecular medicine and will deny access to Medicare recipients to rapidly changing standards of care and treatment for want of an FDA approved assay.

- While the LDT could be considered a 'generic' version of the 'branded' test, that is not an appropriate comparison. With drugs, the challenge is for the 'generic' drug to be 'as good as' the 'branded drug. For lab tests, it is usually the case that the modified FDA test has an enhanced function.

    - Because of the time required for approval, the medical evidence about the test has often evolved and expanded. As noted above, most FDA approved assays originate in commercial development of extant laboratory developed tests, test which have been available for multiple years. While standardization for clinical trials is important, selection of one particular platform as the clinical trial assay does not necessarily mean that it is the optimal assay, and multiple examples exist where the FDA approved assay is analytically inferior to many laboratory developed tests. This is particularly true when laboratory developed assays are adapted to more recent discoveries and understanding, while FDA approved test versions remain locked in their original configurations and indications. Hence, adaptation of FDA approved assays by laboratory Medical Directors often extend the capability of such assays to ensure their clinical usage and validity. I.e. these are "better tests".

    - As noted, it is naïve to restrict the usage of an assay for particular analyte to the single tissue, application or therapy identified in the clinical trial submitted to obtain FDA approval. While such usages may be considered "off label", this should not be viewed as inappropriate, and such laboratory developed adaptations should be appropriately recognized as valid.

Policy Issues

If in fact it is CMS's position that FDA-approved test are the preferred tests and LDTs should be discounted, this should be addressed directly by CMS with public input on the issue, and appropriate amendment to CLIA which authorizes laboratories to develop and implement appropriately validated tests. If CMS and payers have a concern about the quality of tests being performed, the appropriate bodies to address this are the FDA and CMS through CLIA. It is not the purpose of MACs to address issues within the purview of other national bodies. In addition, they do not have the level of expertise and resources to perform this task.

Reimbursement Issues

Requiring the same test to be billed with different codes and then assigning a higher reimbursement for FDA-approved tests compared to the modified-FDA-approved is a major concern.

- It is not consistent with the information statements by the MolDX Program:

> *3. If a test produces similar results, but is performed on different platforms with different costs, will the reimbursement rate be adjusted to show the increase in platform costs? Reimbursement is based on accurate submitted codes regardless of the cost of the platform used. (Source: FAQ/Reimbursement Section)*

- This position does not take into account the actual cost of the service/tests. If the LDT test is a modified-FDA test, the cost of performing the test includes the cost of the FDA-approved test. It also potentially includes additional costs. All these costs should be included in the pricing of the analyte-specific code. This means that the cost of a test using a modified FDA-approved kit is equal to or greater than the FDA-approved test.

- It is in conflict with a fee schedule approach and instructions about establishing payment levels, e.g. the gapfill process. It creates a multi-tiered system of payment for the same test: the FDA-approved tests are individually priced and paid under an NOC code, using the Z-code to trigger the payment level for the NOC code. All other LDT tests are reported under the specific CPT code. This allows the Palmetto to assign a higher level of payment for each of the FDA-approved test. The pricing information for the test reported with the NOC will not be entered into the pricing data for the specific CPT code. It allows Palmetto to assign a lower level of payment for LDTs for the same gene/specific CPT code. EXAMPLE: EGFR

The rationale that the FDA-approved test should be paid higher because it is preferred that all lab test be FDA-approved is invalid and misapplied value judgment. It reflects a 'value' judgment about which tests are 'preferred' and which tests should be 'incentivized', a decision that we believe is outside of the MACs jurisdiction.

Furthermore, the 'value' of the service/test is not one of the factors considered in pricing and a fee schedule system. The purpose of the fee schedule is not to address the 'value' of the service/test or to direct/incentivize 'preferred' tests. It is CMS's responsibility to determine how and if 'value' will be added to the payment system for clinical laboratory tests and applied to all the MACS, including molecular pathology tests.

5. **Coverage and assigned coding for multiple-assay tests with an algorithmic component (MAAA)**
   We believe the MAAA tests are unique tests which provide unique information and serve a distinct clinical benefit. This category of codes was specifically developed to permit tracking of individual MAAAs. We

believe these tests should be covered by Medicare. Furthermore, we believe it is Palmetto's responsibility to implement a coverage and payment policy that is consistent with instructions from CMS about payment for these tests by Medicare.

We believe the coverage and payment for tests that have an algorithmic component that are being instructed to bill using a different NOC code for payment by MolDX Program is in conflict with the position taken by CMS for tests with an algorithmic component. Consequently, we believe this puts the labs at risk for overpayment and other post-payment review actions.

a. The tests that include an algorithm or use of other data evaluation have been assigned a separate CPT code set: The MAAA Codes, administrative multiple-assay tests with an algorithmic component (MAAA); CPT Codes 81500 – 81512, plus 81599.

b. The status of MAAA within the MolDX Program is inconsistent.
    i. The list of CPT codes to which the published LCDs and the MolDX Program is applied does not include the CPT codes that contain the algorithm component: CPT Codes 81500 – 81512, plus NOC code 81599.

    ii. Tests which are multiple-assay tests with an algorithmic component have been reviewed and received a positive coverage decision from the MolDX Program. They have been instructed to bill using an NOC code from another section of the Pathology CPT codes, CPT Code 84999, Unlisted Chemistry Procedure.

    Many of these tests which meet the definition of a MAAA are listed in the published LCDs as covered.
        - Afirma™
        - Allomap
        - Cancer TYPE ID?
        - Corus CAD ®
        - MammaPrint
        - Oncotype DX ® Breast
        - Oncotype DX ® Colon
        - Progensa ® PCA3
        - Tissue-of-Origin
          (Note – there is a related CPT Code 81504: Oncology (tissue of origin), microarray gene expression profiling of > 2000 genes, utilizing formalin-fixed paraffin embedded tissue, algorithm reported as tissue similarity. This is the same definition except the Tissue-of-Origin test profiles 1500 genes)
        - Vectra DA

c. CMS issued a final decision that it does not recognize the new MAAA codes as valid for Medicare purposes under the CLFS for CY 2013.
    - They have instructed laboratories to continue to use the existing HCPCS codes. (New and Reconsidered Clinical Laboratory Fee Schedule (CLFS) Test Codes and Final Payment Determinations dated 11/05/2012.)

- Transmittal 2639 states "Additionally, there were 9 new HCPCS codes for multi-analyte assays with algorithmic analyses (i.e., 81500 through 81512, and 81599) in 2013. The testing described by these codes is subject to the CLIA regulations; however, they are not payable by Medicare for CY 2013. Hence, these 9 codes were not included in this Change Request." (Transmittal 2639 January 25, 2013, MM8162.)

We believe that it is the intention of CMS to not cover any tests with an algorithmic component which would meet the description of the MAAA codes, regardless of whether it has a specific code assigned to it, e.g. a test that should be billed under the NOC code for that section, CPT Code 81599.

d. The MolDX Program's coverage and payment for these tests is in conflict with the CMS national position on MAAA tests. The Program has a responsibility to be consistent with CMS instructions.

> "Contractors are required to ensure that all LCDs are consistent with all statutes, rulings, regulations, and national coverage, payment, and coding policies." [13.1.3 LCDs Para 8]
>
> "The LCD shall be clear, concise, properly formatted and not restrict or conflict with NCDs or coverage provisions in interpretive manuals." [13.5 Content of an LCD
>
> MACS must "ensure that articles do not conflict with NCDs, LCDs, policy, or coverage provisions in interpretive manuals." [PIM 18 §3.3.2.8]

e. *Coding Instructions:* These tests have been assigned an NOC code but not the NOC code associated with MAAA tests, which would be CPT Code 81599. The Program usually instructs them to bill using CPT Code 84999, unlisted chemistry procedure. We believe the assignment of a code outside the MAAA code range circumvents CMS instructions that the testing described is not payable by Medicare. By instructing labs to use an NOC code from another section, they avoid the non-payment status of the NOC code for this section, CPT Code 81599.

f. Palmettos' decision to cover these tests using an unrelated NOC code has serious implications for patient and laboratory liability and future audits.

Expectation of coverage: If the laboratory has a positive coverage decision by the MolDX program with a unique identifier and payment level, the expectation is that they can bill for services and be paid. The beneficiary would be informed that Palmetto does cover the test.

Coverage and Payment using an NOC code from another CPT section:
Selecting an NOC code from another section is not consistent with general coding instructions to providers about how to bill when there is no specific CPT code; they are told to select the NOC code associated with the section in which the procedure/test would fit. If the provider made the decision to use an NOC code from a different section, it could be considered a simple mistake or it could be 'miscoding'. The implications depend on 2 critical questions.

- The first is whether the choice of code affects reimbursement or coverage.

  In this case, the NOC code for the section in which the test belongs would be the MAAAs section, 81599, unlisted multianalyte assay with algorithmic analysis, which would be denied as not payable

by Medicare. An NOC code from another section can be covered and paid. Therefore, the choice of codes does affect payment.

- The second question is whether the provider 'could have or should have known" that the test would not have been covered if it was billed with the MAAAs NOC code.

  In this case, CMS has communicated its position and the codes are not recognized for payment in the database.

Instructing labs to bill for these tests using an NOC code from another section of codes and paying for them puts the lab at risk for overpayment on review [PIM 83 §3.6.1.A], audits and even possible charges of fraud, based on the Medicare statement :

> "In general, fraud is defined as making false statements or representations of material facts to obtain some benefit or payment for which no entitlement would otherwise exist." [1]

We believe that the MolDX Program has created this problem because their coding instructions and coverage and payment practices are in conflict with the national instructions that the MAAA and tests which include an algorithmic component are not payable and CMS instructions to laboratories to bill for the individual components and not the algorithm.

REQUEST:

- We believe it is Palmetto's responsibility to implement CMS instructions that multi-analyte assays with algorithmic analyses are not payable by Medicare.
- We believe the Palmetto should stop coverage and payment for the tests which meet the description of a MAAA under any CPT code.
- The labs should be instructed to follow CMS instructions and bill for the component tests for which they perform the test and develop a test report.
- CMS and Palmetto should clarify the status of any labs that have been billing for tests as instructed by Palmetto. It is inappropriate to leave them hanging, possibly subject to overpayment issues and charges of fraud.

[1] MedLearn - Medicare Fraud & Abuse: Prevention, Detection, and Reporting. http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/Fraud_and_Abuse.pdf Accessed 10/21/2013