



Client Communication

Medicare Local Coverage Determination Policy: CGS

Coverage Policy

L36021 – MoIDX: Molecular Diagnostic Tests (MDT)

CPT: 0004M, 0006M, 0007M, 0011M, 0012M, 0013M, 0016M, 0017M, 0001U, 0005U, 0012U, 0013U, 0014U, 0016U, 0017U, 0018U, 0019U, 0022U, 0023U, 0026U, 0027U, 0029U, 0030U, 0031U, 0032U, 0033U, 0034U, 0036U, 0037U, 0040U, 0045U, 0046U, 0047U, 0048U, 0049U, 0050U, 0055U, 0056U, 0060U, 0069U, 0070U, 0071U, 0072U, 0073U, 0074U, 0075U, 0076U, 0078U, 0079U, 0084U, 0087U, 0088U, 0089U, 0090U, 0091U, 0094U, 0101U, 0102U, 0103U, 0111U, 0113U, 0114U, 0118U, 0120U, 0129U, 0130U, 0131U, 0132U, 0133U, 0134U, 0135U, 0136U, 0137U, 0138U, 0153U, 0154U, 0155U, 0156U, 0157U, 0158U, 0159U, 0160U, 0161U, 0162U, 0168U, 0169U, 0170U, 0171U, 0172U, 0173U, 0175U, 0177U, 0179U, 0180U, 0181U, 0182U, 0183U, 0184U, 0185U, 0186U, 0187U, 0188U, 0189U, 0190U, 0191U, 0192U, 0193U, 0194U, 0195U, 0196U, 0197U, 0198U, 0199U, 0200U, 0201U, 0203U, 0204U, 0205U, 0208U, 0209U, 0211U, 0212U, 0213U, 0214U, 0215U, 0216U, 0217U, 0218U, 0221U, 0222U, 0228U, 0229U, 0230U, 0231U, 0232U, 0233U, 0234U, 0235U, 0236U, 0237U, 0238U, 0239U, 0242U, 0244U, 0245U, 0246U, 0250U, 81105, 81106, 81107, 81108, 81109, 81110, 81111, 81112, 81120, 81121, 81161, 81162, 81163, 81164, 81165, 81166, 81167, 81168, 81170, 81171, 81172, 81173, 81174, 81175, 81176, 81177, 81178, 81179, 81180, 81181, 81182, 81183, 81184, 81185, 81186, 81187, 81188, 81189, 81190, 81191, 81192, 81193, 81194, 81200, 81201, 81202, 81203, 81204, 81205, 81206, 81207, 81208, 81209, 81210, 81212, 81215, 81216, 81217, 81218, 81219, 81220, 81221, 81222, 81223, 81224, 81225, 81226, 81227, 81228, 81229, 81230, 81231, 81232, 81233, 81234, 81235, 81236, 81237, 81238, 81239, 81240, 81241, 81242, 81243, 81244, 81245, 81246, 81247, 81248, 81249, 81250, 81251, 81252, 81253, 81254, 81255, 81256, 81257, 81258, 81259, 81260, 81261, 81262, 81263, 81264, 81265, 81266, 81267, 81268, 81269, 81270, 81271, 81272, 81273, 81274, 81275, 81276, 81277, 81278, 81279, 81283, 81284, 81285, 81286, 81287, 81288, 81289, 81290, 81291, 81292, 81293, 81294, 81295, 81296, 81297, 81298, 81299, 81300, 81301,

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November 2023



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Revision Effective Date: 05/04/2023

Coverage Indications, Limitations, and/or Medical Necessity

As of September 16, 2013 CGS Administrators accepts all coverage determinations made by Palmetto GBA through the MoIDX Program, which are discussed in the details of this policy.

This coverage policy provides the following information:

- defines tests required to register for a unique identifier
- defines tests required to submit a complete technical assessment (TA) for coverage determination
- defines the payment rules applied to covered tests that are not reported with specific codes
- lists specific covered tests that have completed the registration and TA process and meet Medicare's reasonable and necessary criteria for coverage

Tests evaluated through the application process and/or technical assessment will be reviewed to answer the following questions:

- Is the test performed in the absence of clinical signs and symptoms of disease?
- Will the test results provide the clinician with information that will improve patient outcomes and/or change physician care and treatment of the patient?
- Will the test results confirm a diagnosis or known information?
- Is the test performed to determine risk for developing a disease or condition?
- Will risk assessment change management of the patient?

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- Is there a diagnosis specific indication to perform the test?
- Is the test performed to measure the quality of a process or for Quality Control/Quality Assurance (QC/QA), i.e., a test to ensure a tissue specimen matches the patient?

Molecular Diagnostic Test (MDT)

MDT: Any test that involves the detection or identification of nucleic acid(s) deoxyribonucleic acid/ribonucleic acid (DNA/RNA), proteins, chromosomes, enzymes, cancer chemotherapy sensitivity and/or other metabolite(s). The test may or may not include multiple components. A MDT may consist of a single mutation analysis/identification, and/or may or may not rely upon an algorithm or other form of data evaluation/derivation.

LDT: Any test developed by a laboratory developed without FDA approval or clearance.

Applicable Tests/Assays

In addition to the MDT definition, this coverage policy applies to all tests that meet at least one of the following descriptions:

- All non-FDA approved/cleared laboratory developed tests (LDT)
- All modified FDA-approved/cleared kits/tests/assays
- All tests/assays billed with more than one code to identify the service, including combinations of method-based, serology-based, and anatomic pathology codes
- All tests that meet the first three bullets and are billed with an NOC code

Unique Test Identifier Requirement

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

Technology Assessments (TA)

Molecular Diagnostic Services Program (MoIDX®) will review all new test/assay clinical information to determine if a

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test meets Medicare's reasonable and necessary requirement. Labs must submit a comprehensive dossier on each new test/assay prior to claim submission. MoIDX® will only cover and reimburse tests that demonstrate analytical and clinical validity, and clinical utility at a level that meets the Medicare reasonable and necessary requirement.

Payment Rules

MoIDX® will reimburse:

- approved tests covered for dates of service consistent with the effective date of the coverage determination.

Covered Tests

Please refer to the MoIDX® website www.palmettogba.com/MoIDX for covered and excluded tests' specific coding and billing information.

For additional MoIDX® Program information, go to the Medicare home page www.PalmettoGBA.com/MoIDX.

MoIDX® expects laboratory providers to follow test indications published by the developer.

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The ICD10 codes listed below are the top 40 diagnosis codes Sonic most commonly receives from ordering physicians for this limited-coverage test. Medicare supports provider utilization of all the diagnosis codes listed below, except those notated in bold. **If you are providing a diagnosis code that is bolded below, please submit a valid ABN form with the order.** To view the complete policy and the full list of medically supported diagnosis codes, please refer to the CMS website for guidance:

<https://www.cms.gov/medicare-coverage-database/search.aspx>

Codes	Description
Z79.899	Other long term (current) drug therapy
I10	Essential (primary) hypertension
E55.9	Vitamin D deficiency, unspecified
N87.0	Mild cervical dysplasia
R53.83	Other Fatigue
E78.2	Mixed Hyperlipidemia
M06.09	Rheumatoid arthritis without rheumatoid factor, multiple sites
N87.1	Moderate cervical dysplasia
D46.9	Myelodysplastic syndrome, unspecified
M32.10	Systemic lupus erythematosus, organ or system involvement unspecified
D04.61	Carcinoma in situ of skin of right upper limb, including shoulder
Z79.52	Long term (current) use of systemic steroids
R87.810	Cervical high risk human papillomavirus (HPV) DNA test positive
I25.10	Atherosclerotic heart disease of native coronary artery without angina pectoris
Z41.1	Plastic surgery for unacceptable cosmetic appearance
M25.50	Pain in the Unspecified Joint
D64.9	Anemia, Unspecified
K74.60	Unspecified cirrhosis of liver

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M05.79	Rheumatoid arthritis with rheumatoid factor of multiple sites without organ or systems involvement
D75.1	Secondary polycythemia
D49.3	Neoplasm of unspecified behavior of breast
M54.2	Cervicalgia (Neck Pain)
R87.612	Low grade squamous intraepithelial lesion on cytologic smear of cervix (LGSIL)
G62.9	Polyneuropathy, unspecified
N30.01	Acute cystitis with hematuria
H02.64	Xanthelasma of left upper eyelid
R42	Dizziness and Giddiness
D04.39	Carcinoma in situ of skin of other parts of face
T50.905D	Adverse effect of unspecified drugs, medicaments and biological substances, subsequent encounter
D04.5	Carcinoma in situ: Skin of trunk
M79.7	Fibromyalgia
I26.99	Other pulmonary embolism without acute cor pulmonale
N84.0	Polyp of corpus uteri
I48.91	Unspecified atrial fibrillation
N90.89	Other specified noninflammatory disorders of vulva and perineum
I82.401	Acute embolism and thrombosis of unspecified deep veins of right lower extremity
E34.9	Endocrine disorder, unspecified
K62.82	Dysplasia of anus
D68.59	Other primary thrombophilia
E03.9	Hypothyroidism, Unspecified

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