

Measurable (Minimal) Residual Disease Testing



INDEPENDENT CARE HEALTH PLAN

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Medicare Advantage Medical Coverage Policy

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Related Medicare Advantage Medical/Pharmacy Coverage Policies

Comprehensive Genomic Profiling for Hematologic Malignancies

Comprehensive Genomic Profiling for Solid Tumors

Genetic Testing

Genetic Testing for Diagnosis and Monitoring of Cancer

Liquid Biopsy

Related Documents

Please refer to [CMS website](#) for the most current applicable National Coverage Determination (NCD)/Local Coverage Determination (LCD)/Local Coverage Article (LCA)/CMS Online Manual System/Transmittals.

| Type | Title | ID Number | Jurisdiction Medicare Administrative Contractors (MACs) | Applicable States/Territories |
|-------------------------|----------------------------------------------------|------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------|
| NCD | Next Generation Sequencing | 90.2 | | |
| LCD (and pertinent LCA) | MoIDX: Minimal Residual Disease Testing for Cancer | L38779 | JJ, JM - Palmetto GBA | AL, GA, NC, SC, TN, VA, WV |
| LCD (and pertinent LCA) | MoIDX: Minimal Residual Disease Testing for Cancer | L38814 A58996 A58454 A58953 | JE - Noridian Healthcare Solutions, LLC | CA, HI, NV, American Samoa, Guam, Northern Mariana Islands |
| LCD (and pertinent LCA) | MoIDX: Minimal Residual Disease Testing for Cancer | L38816 A58997 A58456 A58954 | JF - Noridian Healthcare Solutions, LLC | AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY |
| LCD (and pertinent LCA) | MoIDX: Minimal Residual Disease Testing for Cancer | L38822 A58998 A58434 A58916 | J15 - CGS Administrators , LLC | KY, OH |
| LCD (and pertinent LCA) | MoIDX: Minimal Residual Disease Testing for Cancer | L38835 | J5 - Wisconsin Physicians Service Insurance Corporation J8 - Wisconsin Physicians Service Insurance Corporation | IA, IN, KS, MI, MO, NE |

Description

Measurable (minimal) Residual Disease (MRD) testing for cancer measures the amount of cancer cells circulating in the blood of cancer patients. Although it is a relatively new application of novel genomic

technologies, MRD testing has demonstrated its ability to impact cancer diagnosis and treatment thus enabling providers to better assign risk stratification, deploy alternate treatment strategies, or reduce the use of unnecessary adjuvant therapies. Examples of MRD testing in hematologic malignancies include, but may not to, ClonoSEQ and MyMRD. Examples of MRD testing in solid tumors include, but may not to, Guardant Reveal, NavDx and Signatera.

Coverage Determination

iCare follows the CMS requirement that only allows coverage and payment for services that are reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member except as specifically allowed by Medicare.

Genetic tests must demonstrate clinical utility, analytical and clinical validity and fulfill the CMS “reasonable and necessary” criteria. Analytic validity (test accurately identifies the gene variant), clinical validity (test identifies or predicts the clinically defined disorder) and clinical utility (test measurably improves clinical outcomes) of the genetic test is supported by generally accepted standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, specialty society recommendations, and views of physicians practicing in relevant clinical areas. The test must be ordered by a physician who is treating the beneficiary and the results will be used in the management of a beneficiary’s specific medical problem.

For jurisdictions with no Medicare guidance, iCare will utilize the [MolDX Program](#) and Technical Assessments for molecular assays as the standard to evaluate clinical utility, analytical and clinical validity in conjunction with adhering to Medicare’s reasonable and necessary requirement.

In interpreting or supplementing the criteria above and in order to determine medical necessity consistently, iCare may consider the following criteria:

General Measurable (Minimal) Residual Disease

MRD testing will be considered medically reasonable and necessary when all the following requirements are met:

- If Next Generation Sequencing (NGS) methodology is used in testing, the conditions set by NCD 90.2 are fulfilled; **AND**
- Individual has a personal history of cancer, the type and staging of which is within the intended use of the MRD test; **AND**
- The identification of recurrence or progression of disease within the intended use population of the test is identified in the National Comprehensive Cancer Network (NCCN) or other established guidelines as a condition that requires a definitive change in the individual’s management; **AND**
- The test is demonstrated to identify molecular recurrence or progression before there is clinical, biological, or radiographical evidence of recurrence or progression AND demonstrates sensitivity and specificity of subsequent recurrence or progression comparable with or superior to radiographical or other evidence (as per the standard-of-care for monitoring a given cancer type) of recurrence or progression; **AND**

- To be reasonable and necessary, it must also be medically acceptable that the test being utilized precludes other surveillance or monitoring tests intended to provide the same or similar information, unless either of the following:
 - Required to follow-up or confirm the findings of this test; **OR**
 - Medically required for further assessment and management of the individual; **AND**
- If the test is to be used for monitoring a specific therapeutic response, it must demonstrate the clinical validity of its results in published literature for the explicit management or therapy indication (allowing for the use of different drugs within the same therapeutic class, so long as they are considered equivalent and interchangeable for the purpose of MRD testing, as determined by national or society guidelines); **AND**
- Tests utilizing a similar methodology or evaluating a similar molecular analyte to a test for which there is a generally accepted testing standard or for which existing coverage exists must demonstrate equivalent or superior test performance (eg, sensitivity and/or specificity) when used for the same indication in the same intended use population

Measurable (Minimal) Residual Disease Testing for Solid Tumors

MRD testing for solid tumors using Guardant Reveal or Signatera [0340U]) will be considered medically reasonable and necessary when the general MRD criteria listed above and all the following requirements are met:

- Individual diagnosed with bladder cancer that has spread into the muscle of the bladder (stage II or III); **OR**
- Individual diagnosed with breast cancer (stage IIb or III); **OR**
- Individual diagnosed with colon cancer that has spread through the wall of the colon/rectum (stage II-IV); **OR**
- Monitoring an individual's response to current immune checkpoint inhibitor therapy for any solid tumor

Measurable (Minimal) Residual Disease for Hematologic Malignancies

MRD testing for hematologic malignancies will be considered medically reasonable and necessary when the general MRD criteria listed above and all the following requirements are met:

- Baseline assessment, suspected relapse or prior to induction for any of the following:
 - Acute lymphoblastic leukemia
 - Acute myeloid leukemia
 - Chronic lymphoblastic leukemia/ Small Lymphocytic Lymphoma
 - Chronic Myeloid Leukemia
 - Diffuse Large B-Cell Lymphoma
 - Multiple myeloma

The use of the criteria in this Medicare Advantage Medical Coverage Policy provides clinical benefits highly likely to outweigh any clinical harms. Services that do not meet the criteria above are not medically necessary and thus do not provide a clinical benefit. Medically unnecessary services carry risks of adverse outcomes and may interfere with the pursuit of other treatments which have demonstrated efficacy.

Coverage Limitations

[US Government Publishing Office. Electronic code of federal regulations: part 411 – 42 CFR § 411.15 - Particular services excluded from coverage](#)

The following services/items will not be considered medically reasonable and necessary:

- Genetic tests that have not demonstrated clinical utility, analytical and clinical validity via the [MoIDX Program](#)
- Repeat testing solely for screening or surveillance in hematologic malignancies
- Testing to detect a second primary tumor, including 1 located within the same organ (eg, 2 separate primary lung tumors)
- Insufficient ctDNA molecules in the plasma (or other tested compartment), a special consideration particularly in an individual with smaller or less aggressive cancers

A review of the current medical literature shows that the evidence is insufficient to determine that this service is standard medical treatment for these indications. There remains an absence of randomized blinded clinical studies examining benefit and long-term clinical outcomes establishing the value of this service in clinical management for these indications.

Screening services such as presymptomatic genetic tests and services used to detect and undiagnosed diseased or disease predisposition are not a Medicare benefit and are not covered.

The following test types are examples of testing services that may not be considered a benefit (statutory excluded) and denied as Medicare Excluded tests²⁷:

- Tests considered screening in the absence of clinical signs and symptoms of disease that are not specifically identified by the law; **OR**
- Tests that confirm a diagnosis or known information; **OR**
- Tests to determine risk for developing a disease or condition; **OR**
- Tests performed to measure the quality of a process; **OR**
- Tests without diagnosis specific indications; **OR**

- Tests identified as investigational by available literature and/or the literature supplied by the developer and are not a part of a clinical trial

Coding Information

Any codes listed on this policy are for informational purposes only. Do not rely on the accuracy and inclusion of specific codes. Inclusion of a code does not guarantee coverage and/or reimbursement for a service or procedure.

| CPT® Code(s) | Description | Comments |
|--------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------|
| 81206 | BCR/ABL1 (t(9;22)) (eg, chronic myelogenous leukemia) translocation analysis; major breakpoint, qualitative or quantitative | |
| 81207 | BCR/ABL1 (t(9;22)) (eg, chronic myelogenous leukemia) translocation analysis; minor breakpoint, qualitative or quantitative | |
| 81208 | BCR/ABL1 (t(9;22)) (eg, chronic myelogenous leukemia) translocation analysis; other breakpoint, qualitative or quantitative | |
| 81261 | IGH@ (Immunoglobulin heavy chain locus) (eg, leukemias and lymphomas, B-cell), gene rearrangement analysis to detect abnormal clonal population(s); amplified methodology (eg, polymerase chain reaction) | |
| 81263 | IGH@ (Immunoglobulin heavy chain locus) (eg, leukemia and lymphoma, B-cell), variable region somatic mutation analysis | |
| 81264 | IGK@ (Immunoglobulin kappa light chain locus) (eg, leukemia and lymphoma, B-cell), gene rearrangement analysis, evaluation to detect abnormal clonal population(s) | |
| 81310 | NPM1 (nucleophosmin) (eg, acute myeloid leukemia) gene analysis, exon 12 variants | |
| 81315 | PML/RARalpha, (t(15;17)), (promyelocytic leukemia/retinoic acid receptor alpha) (eg, promyelocytic leukemia) translocation analysis; common breakpoints (eg, intron 3 and intron 6), qualitative or quantitative | |
| 81316 | PML/RARalpha, (t(15;17)), (promyelocytic leukemia/retinoic acid receptor alpha) (eg, promyelocytic leukemia) translocation analysis; single breakpoint (eg, intron 3, intron 6 or exon 6), qualitative or quantitative | |
| 81334 | RUNX1 (runt related transcription factor 1) (eg, acute myeloid leukemia, familial platelet disorder with associated myeloid malignancy), gene analysis, targeted sequence analysis (eg, exons 3-8) | |

| | | |
|-------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|
| 81340 | TRB@ (T cell antigen receptor, beta) (eg, leukemia and lymphoma), gene rearrangement analysis to detect abnormal clonal population(s); using amplification methodology (eg, polymerase chain reaction) | |
| 81342 | TRG@ (T cell antigen receptor, gamma) (eg, leukemia and lymphoma), gene rearrangement analysis, evaluation to detect abnormal clonal population(s) | |
| 81401 | MOLECULAR PATHOLOGY PROCEDURE LEVEL 2 | |
| 81445 | Targeted genomic sequence analysis panel, solid organ neoplasm, 5-50 genes (eg, ALK, BRAF, CDKN2A, EGFR, ERBB2, KIT, KRAS, MET, NRAS, PDGFRA, PDGFRB, PGR, PIK3CA, PTEN, RET), interrogation for sequence variants and copy number variants or rearrangements, if performed; DNA analysis or combined DNA and RNA analysis | |
| 81450 | Targeted genomic sequence analysis panel, hematolymphoid neoplasm or disorder, 5-50 genes (eg, BRAF, CEBPA, DNMT3A, EZH2, FLT3, IDH1, IDH2, JAK2, KIT, KRAS, MLL, NOTCH1, NPM1, NRAS), interrogation for sequence variants, and copy number variants or rearrangements, or isoform expression or mRNA expression levels, if performed; DNA analysis or combined DNA and RNA analysis | |
| 81479 | Unlisted molecular pathology procedure | |
| 0040U | BCR/ABL1 (t(9;22)) (eg, chronic myelogenous leukemia) translocation analysis, major breakpoint, quantitative | |
| 0046U | FLT3 (fms-related tyrosine kinase 3) (eg, acute myeloid leukemia) internal tandem duplication (ITD) variants, quantitative | |
| 0171U | Targeted genomic sequence analysis panel, acute myeloid leukemia, myelodysplastic syndrome, and myeloproliferative neoplasms, DNA analysis, 23 genes, interrogation for sequence variants, rearrangements and minimal residual disease, reported as presence/absence | |
| 0306U | Oncology (minimal residual disease [MRD]), next-generation targeted sequencing analysis, cell-free DNA, initial (baseline) assessment to determine a patient-specific panel for future comparisons to evaluate for MRD | |
| 0307U | Oncology (minimal residual disease [MRD]), next-generation targeted sequencing analysis of a patient-specific panel, cell-free DNA, subsequent assessment with comparison to previously analyzed patient specimens to evaluate for MRD | |
| 0340U | Oncology (pan-cancer), analysis of minimal residual disease (MRD) from plasma, with assays personalized to each patient based on prior next-generation sequencing of the patient's tumor and germline DNA, reported as absence or presence of MRD, with disease-burden correlation, if appropriate | |

| 0356U | Oncology (oropharyngeal), evaluation of 17 DNA biomarkers using droplet digital PCR (ddPCR), cell-free DNA, algorithm reported as a prognostic risk score for cancer recurrence | |
|------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|
| 0364U | Oncology (hematolymphoid neoplasm), genomic sequence analysis using multiplex (PCR) and next-generation sequencing with algorithm, quantification of dominant clonal sequence(s), reported as presence or absence of minimal residual disease (MRD) with quantitation of disease burden, when appropriate | |
| CPT® Category III Code(s) | Description | Comments |
| No code(s) identified | | |
| HCPCS Code(s) | Description | Comments |
| No code(s) identified | | |

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Change Summary

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