Local Coverage Determination (LCD): MolDX: Cystatin C Measurement (L37616)

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Contractor Information

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATE(S)
Noridian Healthcare Solutions, LLC	A and B MAC	01111 - MAC A	J - E	California - Entire State
Noridian Healthcare Solutions, LLC	A and B MAC	01112 - MAC B	J - E	California - Northern
Noridian Healthcare Solutions, LLC	A and B MAC	01182 - MAC B	J - E	California - Southern
Noridian Healthcare Solutions, LLC	A and B MAC	01211 - MAC A	J - E	American Samoa Guam Hawaii Northern Mariana Islands
Noridian Healthcare Solutions, LLC	A and B MAC	01212 - MAC B	J - E	American Samoa Guam Hawaii Northern Mariana Islands
Noridian Healthcare Solutions, LLC	A and B MAC	01311 - MAC A	J - E	Nevada
Noridian Healthcare Solutions, LLC	A and B MAC	01312 - MAC B	J - E	Nevada
Noridian Healthcare Solutions, LLC	A and B MAC	01911 - MAC A	J - E	American Samoa California - Entire State Guam Hawaii Nevada Northern Mariana Islands

LCD Information

Document Information

LCD ID **Original Effective Date**

L37616

For services performed on or after 02/11/2019

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MolDX: Cystatin C Measurement

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N/A

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N/A

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N/A

AMA CPT / ADA CDT / AHA NUBC Copyright Statement

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12/27/2018

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02/10/2019

CMS National Coverage Policy

Title XVIII of the Social Security Act, §1862(a)(1)(A). Allows coverage and payment for only those services that are

considered to be reasonable and necessary.
Title XVIII of the Social Security Act, §1833(e). Prohibits Medicare payment for any claim which lacks the necessary information to process the claim.
42 Code of Federal Regulations (CFR) 410.32(a). Diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests: Conditions.
CMS On-Line Manual, Publication 100-02, Medicare Benefit Policy Manual, Chapter 15, §§80.0, 80.1.1, 80.2. Clinical Laboratory services.
CMS Internet-Only Manuals, Publication 100-04, Medicare Claims Processing Manual, Chapter 16, §50.5 Jurisdiction of Laboratory Claims, 60.12 Independent Laboratory Specimen Drawing, 60.2. Travel Allowance.
CMS Internet Online Manual Pub. 100-04 (Medicare Claims Processing Manual), Chapter 23 (Section 10) "Reporting ICD Diagnosis and Procedure Codes".

Coverage Guidance

Coverage Indications, Limitations, and/or Medical Necessity

History/Background and/or general information

Cystatin C is a low molecular weight protein produced by all nucleated cells in the body at a constant rate. Cystatin C is freely filtered by the renal glomerulus, completely reabsorbed by the proximal tubule, and then metabolized by the proximal tubule. It has been proposed and investigated as an improved marker of renal function and as a potential alternative to serum creatinine based estimated glomerular filtration rate (eGFR), as well as a biomarker for predicting cardiovascular risk.

Clinical assessment of kidney function is part of routine medical care for adults. GFR is the best overall index of kidney function. Normal GFR varies according to age, sex, and body size, and declines with age. Routinely, GFR is estimated from prediction equations which are based on endogenous serum markers like creatinine in addition to demographic variables such as age, sex and race. The National Kidney Foundation recommends using the Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) Creatinine Equation (2009) to estimate GFR.

Cystatin C is considered to be a potential alternative to serum creatinine for estimating GFR. GFR can be estimated (eGFR) from serum cystatin C utilizing an equation which includes the age and gender of the patient. Cystatin C eGFR may have advantages over creatinine eGFR in certain patient groups in whom muscle mass is abnormally high or low (e.g., individuals who are very elderly, malnourished, or have quadriplegia). Serum creatinine levels may also be influenced by diet (e.g., vegetarian or high protein diets) and medications that block distal tubule secretion of creatinine. Blood levels of cystatin C also equilibrate more quickly than creatinine. Therefore, serum cystatin C may be more accurate than serum creatinine when kidney function is rapidly changing (for example amongst hospitalized individuals).

Cystatin C levels have been reported to be abnormally elevated or decreased in some medical conditions (e.g., HIV disease and thyroid disease) and by some medications (e.g., corticosteroids). In clinical situations where confirmation of the eGFR by serum cystatin C is warranted, equations that combine serum cystatin C and serum creatinine provide a more precise eGFR than equations using serum cystatin C alone.

Estimation of GFR from serum creatinine remains the clinical standard worldwide.

Covered Indications

Cystatin C testing is medically reasonable and necessary when all of the following are met:

- In adults with eGFRcreat 45–59 ml/min/1.73 m2 (CKD stage 3A mildly to moderately decreased GFR) who do not have markers of kidney damage; **and**
- If confirmation is warranted
    - When GFR estimates based on serum creatinine are thought to be inaccurate; **and**
    - When decisions depend on a more accurate knowledge of the GFR, such as confirming a diagnosis of chronic kidney disease (CKD), determining eligibility for kidney donation, or adjusting the dosage of toxic drugs that are excreted by the kidneys).

Limitations

The following are not reasonable and necessary and therefore will be denied:

- Measurement of cystatin C to assess cardiovascular risk is considered investigational in the risk assessment and management of cardiovascular disease. Cystatin C is not covered according to Title XVIII of the Social Security Act, Section 1861(xx)(1). Therefore, cystatin C measurement is considered not medically reasonable and necessary.
- Based on the Kidney Disease Outcomes Quality Initiative (KDOQI) US Commentary on the 2012 Kidney Disease: Improving Global Outcomes (KDIGO) Clinical Practice Guideline for the Evaluation and Management of CKD, cystatin C testing is considered not medically reasonable and necessary for patients with following stages of CKD:
    - Stage 1 Kidney damage with normal or elevated GFR > 90 ml/min/1.73 m^2
    - Stage 2 Kidney damage with mild decrease in GFR 60-89 ml/min/1.73 m^2
    - Stage 3B Moderately to Severely decreased GFR 30-44 ml/min/1.73 m^2
    - Stage 4 Severely decreased GFR 15-29 ml/min/1.73 m^2
    - Stage 5 Kidney Failure GFR < 15 ml/min/1.73 m^2

Summary of Evidence

Evidence-based clinical guidelines.

KDIGO 2012 Clinical Practice Guideline for the Evaluation and Management of Chronic Kidney Disease

"The Kidney Disease: Improving Global Outcomes (KDIGO) 2012 Clinical Practice Guideline for the Evaluation and Management of Chronic Kidney Disease (CKD) serves to update the 2002 KDOQI Clinical Practice Guidelines for Chronic Kidney Disease: Evaluation, Classification, and Stratification following a decade of focused research and clinical practice in CKD. The document aims to provide state-of-the-art guidance on the evaluation, management and treatment for all patients with CKD. Specifically, the guideline retains the definition of CKD but presents an enhanced classification framework for CKD; elaborates on the identification and prognosis of CKD; discusses the management of progression and complications of CKD; and expands on the continuum of CKD care: timing of specialist referral, ongoing management of people with progressive CKD, timing of the initiation of dialysis, and finally the implementation of a treatment program which includes comprehensive conservative management. The development of the guideline followed an explicit process of evidence review and appraisal. Treatment approaches are addressed in each chapter and guideline recommendations are based on systematic reviews of relevant trials. Practical comments or statements which serve as educational purposes are ungraded, but included as important information for the readership. Appraisal of the quality of the evidence and the strength of recommendations followed the GRADE approach. Ongoing areas of controversies, limitations of the evidence, and international relevance are discussed and additional suggestions are provided for future research."

The guideline recommends using serum creatinine and a GFR estimating equation for initial assessment of CKD. It suggests using additional tests (such as cystatin C or a clearance measurement) for confirmatory testing in specific circumstances when eGFR based on serum creatinine is less accurate. Confirmation of a decreased eGFR is warranted in specific circumstances where decisions depend on more accurate knowledge of the GFR, such as confirming a diagnosis of CKD, determining eligibility for kidney donation, or adjusting the dosage of toxic drugs that are excreted by the kidneys. It also suggests measuring cystatin C in adults with eGFRcreat 45–59 ml/min/1.73 m2 who do not have markers of kidney damage if confirmation of CKD is required. Another suggestion is measuring GFR using an exogenous filtration marker under circumstances where more accurate ascertainment of GFR will impact on treatment decisions.

KDOQI US Commentary on the 2012 KDIGO Clinical Practice Guideline for the Evaluation and Management of CKD

"The National Kidney Foundation–Kidney Disease Outcomes Quality Initiative (NKF-KDOQI) guideline for evaluation, classification, and stratification of chronic kidney disease (CKD) was published in 2002. The KDOQI guideline was well accepted by the medical and public health communities, but concerns and criticisms arose as new evidence became available since the publication of the original guidelines. KDIGO (Kidney Disease: Improving Global Outcomes) recently published an updated guideline to clarify the definition and classification of CKD and to update recommendations for the evaluation and management of individuals with CKD based on new evidence published since 2002. The primary recommendations were to retain the current definition of CKD based on decreased glomerular filtration rate or markers of kidney damage for 3 months or more and to include the cause of kidney disease and level of albuminuria, as well as level of glomerular filtration rate, for CKD classification. NKF-KDOQI convened a work group to write a commentary on the KDIGO guideline in order to assist US practitioners in interpreting the KDIGO guideline and determining its applicability within their own practices. Overall, the commentary work group agreed with most of the recommendations contained in the KDIGO guidelines, particularly the recommendations regarding the definition and classification of CKD. However, there were some concerns about incorporating the cause of disease into CKD classification, in addition to certain recommendations for evaluation and management."

The guideline states estimation of GFR from serum creatinine remains the clinical standard worldwide. It also recognizes the limitations of creatinine and recommends additional confirmatory tests, such as measurement of cystatin C or clearance, in situations when estimates of GFR from serum creatinine are less accurate. For the purposes of estimation of measured GFR, the combination of both markers (cystatin C and creatinine) provides a more precise estimate. The guideline agrees that GFR estimation using cystatin C alone or in combination with creatinine is useful as a confirmatory test of eGFR from creatinine, and that it improves risk stratification.

National Academy of Clinical Biochemistry Laboratory Medicine Practice Guidelines: Emerging Biomarkers for Primary Prevention of Cardiovascular Disease

The guidelines state cystatin C may be a more powerful predictor of cardiovascular events than eGFR calculation based on creatinine and recommends additional research to determine if interventions based on cystatin C measurements for risk stratification will provide added clinical benefit. Also, the guidelines state cystatin C has been proposed and investigated as an improved marker of renal function, a potential alternative to serum creatinine based estimated GFR, and the results of a meta-analysis support serum cystatin C as a promising, easily measured marker for detecting early kidney function impairment.

2010 ACCF/AHA Guideline for Assessment of Cardiovascular Risk in Asymptomatic Adults: Executive Summary

The American College of Cardiology Foundation (ACCF) and the American Heart Association (AHA) state "Global risk scores (such as the Framingham Risk Score [FRS]) that use multiple traditional cardiovascular risk factors should be obtained for risk assessment in all asymptomatic adults without a clinical history of CHD. These scores are useful for combining individual risk factor measurements into a single quantitative estimate of risk that can be used to target preventive interventions."

Cystatin C is not referenced in the guideline. Therefore, there are no recommendations for cystatin C testing for cardiovascular risk assessment.

2013 ACC/AHA Cardiovascular Risk Assessment Guideline

Members of the American College of Cardiology (ACC) and the American Heart Association (AHA) Work Group proposed an initial list of novel risk markers for inclusion in critical question 1 (CQ1), which was then prioritized during several rounds of discussion. In selecting the final list, the Work Group gave priority to factors that have engendered substantial discussion in the scientific community and that could be reasonably considered as potentially feasible for widespread population use by primary care providers in routine clinical settings in the United States. In these deliberations, the Work Group considered availability, cost, assay reliability, and risks of the test or downstream testing. The final list of new risk markers to be evaluated included several blood and urine biomarkers (hs-CRP [high-sensitivity C-reactive protein], ApoB [Apolipoprotein B], creatinine [or eGFR], and microalbuminuria), several measures of subclinical cardiovascular disease (CAC [coronary artery calcium], CIMT [carotid intima-media thickness], and ABI [ankle brachial index]), family history, and cardiorespiratory fitness. It was noted that measurement of ApoB, albuminuria, GFR, or cardiorespiratory fitness is of uncertain value. The contribution of ApoB, CKD, albuminuria, and cardiorespiratory fitness to risk assessment for a first atherosclerotic cardiovascular disease (ASCVD) event is uncertain at present.

Cystatin C is not referenced in the guideline. Therefore, there are no recommendations for cystatin C testing for cardiovascular risk assessment.

Analysis of Evidence
(Rationale for Determination)

Analysis of Evidence
(Rationale for Determination)

The guideline from the National Kidney Foundation supports that estimation of GFR from serum creatinine remains the clinical standard worldwide. However, it acknowledges the limitations of serum creatinine and agrees with the KDIGO 2012 Clinical Practice Guideline suggestions for use of serum cystatin C as a confirmatory test for eGFR when estimates of GFR from serum creatinine are less accurate in adults with $eGFR_{creat}$ 45–59 ml/min/1.73 m2 who do not have markers of kidney damage and if confirmation is warranted.

Title XVIII of the Social Security Act, Section 1861(xx)(1) Cardiovascular Screening Blood Test does not include Cystatin C measurement as a covered service. The American College of Cardiology Foundation (ACCF), American College of Cardiology (ACC) and the American Heart Association (AHA) guidelines do not support serum cystatin C testing for cardiovascular risk assessment.

Coding Information

Bill Type Codes:

Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the policy does not apply to that Bill Type.Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally to all claims.

CODE	DESCRIPTION
012x	Hospital Inpatient (Medicare Part B only)
013x	Hospital Outpatient
014x	Hospital - Laboratory Services Provided to Non-patients
022x	Skilled Nursing - Inpatient (Medicare Part B only)
023x	Skilled Nursing - Outpatient
071x	Clinic - Rural Health
072x	Clinic - Hospital Based or Independent Renal Dialysis Center
075x	Clinic - Comprehensive Outpatient Rehabilitation Facility (CORF)
077x	Clinic - Federally Qualified Health Center (FQHC)
085x	Critical Access Hospital

Revenue Codes:

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory. Unless specified in the policy, services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally to all Revenue Codes.

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory. Unless specified in the policy, services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally to all Revenue Codes.

Note: The contractor has identified the Bill Type and Revenue Codes applicable for use with the CPT/HCPCS codes included in this LCD. Providers are reminded that not all CPT/HCPCS codes listed can be billed with all Bill Type and/or Revenue Codes listed. CPT/HCPCS codes are required to be billed with specific Bill Type and Revenue Codes. Providers are encouraged to refer to the CMS Internet-Only Manual (IOM) Pub. 100-04, Claims Processing Manual, for further guidance.

CODE	DESCRIPTION
030X	Laboratory - General Classification
031X	Laboratory Pathology - General Classification

CPT/HCPCS Codes

Group 1 Paragraph:

N/A

Group 1 Codes:

CODE	DESCRIPTION
82610	CYSTATIN C

ICD-10 Codes that Support Medical Necessity

Group 1 Paragraph:

N/A

Group 1 Codes:

ICD-10 CODE	DESCRIPTION
N18.3	Chronic kidney disease, stage 3 (moderate)
T50.904A	Poisoning by unspecified drugs, medicaments and biological substances, undetermined, initial encounter
T50.904D	Poisoning by unspecified drugs, medicaments and biological substances, undetermined, subsequent encounter
T50.904S	Poisoning by unspecified drugs, medicaments and biological substances, undetermined, sequela
T50.905A	Adverse effect of unspecified drugs, medicaments and biological substances, initial encounter
T50.905D	Adverse effect of unspecified drugs, medicaments and biological substances, subsequent encounter
T50.905S	Adverse effect of unspecified drugs, medicaments and biological substances, sequela
T50.994A	Poisoning by other drugs, medicaments and biological substances, undetermined, initial encounter
T50.994D	Poisoning by other drugs, medicaments and biological substances, undetermined, subsequent encounter
T50.994S	Poisoning by other drugs, medicaments and biological substances, undetermined, sequela

ICD-10 CODE	DESCRIPTION
T50.995A	Adverse effect of other drugs, medicaments and biological substances, initial encounter
T50.995D	Adverse effect of other drugs, medicaments and biological substances, subsequent encounter
T50.995S	Adverse effect of other drugs, medicaments and biological substances, sequela
T65.94XA	Toxic effect of unspecified substance, undetermined, initial encounter
T65.94XD	Toxic effect of unspecified substance, undetermined, subsequent encounter
T65.94XS	Toxic effect of unspecified substance, undetermined, sequela
Z52.4	Kidney donor

ICD-10 Codes that DO NOT Support Medical Necessity

N/A

Additional ICD-10 Information

N/A

General Information

Associated Information

Documentation Requirements

1. All documentation must be maintained in the patient's medical record and made available to the contractor upon request.
2. Every page of the record must be legible and include appropriate patient identification information (e.g., complete name, dates of service(s)). The documentation must include the legible signature of the physician or non-physician practitioner responsible for and providing the care to the patient.
3. The submitted medical record must support the use of the selected ICD-10-CM code(s). The submitted CPT/HCPCS code must describe the service performed.
4. The medical record documentation must support the medical necessity of the services as directed in this policy.
5. The laboratory or billing provider must have on file the physician requisition which sets forth the diagnosis or condition (ICD-10-CM code) that warrants the test(s).
6. Examples of documentation requirements of the ordering physician/non-physician practitioner (NPP) include, but are not limited to, history and physical or exam findings that support the decision making, problems/diagnoses, relevant data (e.g., lab testing).
7. Medical record documentation must support cystatin C test was performed on an adult patient with creatinine based eGFR 45–59 ml/min/1.73 m2 who does not have markers of kidney damage.
8. Medical record documentation must clearly indicate the rationale which supports the medical necessity for performing eGFR by measurement of cystatin C (i.e. support GFR estimates based on serum creatinine are thought to be inaccurate and what decisions depend on more accurate knowledge of the GFR) and must reflect how the test result were used in the patient’s plan of care.

Utilization Guidelines

In accordance with CMS Ruling 95-1 (V), utilization of these services should be consistent with locally acceptable standards of practice.

Cystatin C testing will be considered medically reasonable and necessary when furnished as a confirmatory test in specific circumstances when eGFR based on serum creatinine is less accurate (e.g. muscle mass is abnormally high or low, dietary intake, medications that block distal tubule secretion of creatinine) and when more accurate knowledge of the eGFR will impact decisions, such as confirming a diagnosis of CKD, determining eligibility for kidney donation, or adjusting the dosage of toxic drugs that are excreted by the kidneys.

Repetitive use of cystatin C testing without documented evidence supporting the medical necessity would not be expected.

When services are performed in excess of established parameters, they may be subject to prepayment review for medical necessity.

Sources of Information

N/A

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Revision History Information

N/A

Associated Documents

Attachments

N/A

Related Local Coverage Documents

Article(s)

A56211 - Response to Comments: MolDX: Cystatin C Measurement

LCD(s)

DL37616 - MolDX: Cystatin C Measurement

Related National Coverage Documents

N/A

Public Version(s)

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