

Local Coverage Determination (LCD): MoIDX: Repeat Germline Testing (L38351)

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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

L38351

For services performed on or after 08/03/2020

LCD Title

MoIDX: Repeat Germline Testing

Revision Effective Date

N/A

Proposed LCD in Comment Period

N/A

Revision Ending Date

N/A

Source Proposed LCD

DL38351

Retirement Date

N/A

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Notice Period Start Date

06/18/2020

Notice Period End Date

08/02/2020

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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.

42 Code of Federal Regulations (CFR) 410.32(a). Diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests: Conditions.

CMS Internet-Only Manuals, Pub 100-02, Medicare Benefit Policy Manual, Chapter 15, §§80.0, 80.1.1, 80.2. Clinical Laboratory services.

CMS Internet-Only Manuals, Pub 100-04, Medicare Claims Processing Manual, Chapter 16, §50.5 Jurisdiction of Laboratory Claims, 60.1.2 Independent Laboratory Specimen Drawing, 60.2. Travel Allowance.

Coverage Guidance

Coverage Indications, Limitations, and/or Medical Necessity

This Medicare contractor herein identifies general limitations to coverage of DNA and RNA-based testing of germline genetic material of the Medicare beneficiary.

This contractor does not consider any laboratory test that investigates the same germline genetic content, for the same genetic information, that has already been tested in the same Medicare beneficiary to be reasonable and necessary as it is duplicative.

Germline testing, including using gene panels that contain some genetic content that has already been tested in the same Medicare beneficiary may be considered reasonable and necessary provided that there is established clinical utility present in the remaining, non-duplicative genetic components of the test. Unit of Service (UOS) for any one specific germline DNA or RNA-based test is limited to one per lifetime. Examples of germline tests include (but are not limited to) single gene and gene panel tests for: hereditary cancer syndromes or cancer predisposition, inherited disorders, and pharmacogenomics/cytochrome P450 testing.

Providers should take reasonable measures to be aware of what if any germline testing a beneficiary has had prior to billing for germline testing so as to avoid billing Medicare for services that are not reasonable and necessary. Clinicians who order germline testing may wish to be aware of whether the test that they are ordering is covered under Medicare and may wish to verify that they are not ordering repeat germline testing.

Summary of Evidence

Background

Patient DNA and RNA testing typically identify alterations or variants of nucleotides in the genetic code, which can range from pathogenic mutations to benign polymorphisms. These alterations can take the form of single nucleotide variants, insertions and/or deletions, splice-site variants, copy number alterations of genes or chromosomes, and inversions or translocations, among others¹. They can be found in coding regions or non-coding regions. Germline testing is differentiated from somatic testing in that somatic testing identifies alterations specific to an individual cell or group of cells derived from that cell (such as a neoplasm or clonal hematopoietic cells) whereas germline testing seeks to identify inherited variants or alleles that are present in all the patient's cells and make up a baseline genetic code of the individual². Although somatic alterations are constantly occurring during the life of an individual, the germline sequence of an individual does not change over time.

Clinical utility of germline testing in Medicare beneficiaries has previously been established for several conditions³⁻⁷. However, as repeated testing of the same genetic information does not by its nature provide new clinical information, this contractor does not believe it is either reasonable or necessary to perform such services more than once.

Analysis of Evidence (Rationale for Determination)

Level of Evidence

Quality of evidence – Strong

Strength of evidence – Strong

Weight of evidence – Strong

By definition, germline alleles/variants do not change. Some allowance must be made for incidental repeat testing or for specific situations where technological changes require revisiting the same genomic regions with different approaches or targets. For more details, please review the associated Billing and Coding Article.

General Information

Associated Information

N/A

Sources of Information

N/A

Bibliography

1. Kassem, H., F. Girolami, and D. Sanoudou, *Molecular genetics made simple*. Glob Cardiol Sci Pract, 2012.

- 2012(1): p. 6.
2. Griffiths A.J.F., M.J.H., Suzuki D.T., et al., *Introduction to Genetic Analysis*. 7th ed. ed. 2000, New York: W. H. Freeman.
 3. Network, N.C.C. *NCCN Guidelines Version 2.2018*, [Colon Cancer](#). 2019. Accessed on 07/11/19.
 4. Network, N.C.C. *NCCN Guidelines Version 2.2018*, [Ovarian Cancer](#). 2019. Accessed on 07/11/19.
 5. Yadav, S. and F.J. Couch, *Germline Genetic Testing for Breast Cancer Risk: The Past, Present, and Future*. American Society of Clinical Oncology Educational Book, 2019(39): p. 61-74.
 6. Cheng, H., et al., *Practical Methods for Integrating Genetic Testing Into Clinical Practice for Advanced Prostate Cancer*. American Society of Clinical Oncology Educational Book, 2018(38): p. 372-381.
 7. Ballester, V. and M. Cruz-Correa, *How and When to Consider Genetic Testing for Colon Cancer?* *Gastroenterology*, 2018. 155(4): p. 955-959.
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Revision History Information

N/A

Associated Documents

Attachments

N/A

Related Local Coverage Documents

Article(s)

A57331 - Billing and Coding: MoIDX: Repeat Germline Testing

A58176 - Response to Comments: MoIDX: Repeat Germline Testing

LCD(s)

DL38351 - MoIDX: Repeat Germline Testing

Related National Coverage Documents

N/A

Public Version(s)

Updated on 06/02/2020 with effective dates 08/03/2020 - N/A

Keywords

N/A