LCD - MolDX: Repeat Germline Testing (L38353)

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Contractor Information

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATES
Noridian Healthcare Solutions, LLC	A and B MAC	02101 - MAC A	J - F	Alaska
Noridian Healthcare Solutions, LLC	A and B MAC	02102 - MAC B	J - F	Alaska
Noridian Healthcare Solutions, LLC	A and B MAC	02201 - MAC A	J - F	Idaho
Noridian Healthcare Solutions, LLC	A and B MAC	02202 - MAC B	J - F	Idaho
Noridian Healthcare Solutions, LLC	A and B MAC	02301 - MAC A	J - F	Oregon
Noridian Healthcare Solutions, LLC	A and B MAC	02302 - MAC B	J - F	Oregon
Noridian Healthcare Solutions, LLC	A and B MAC	02401 - MAC A	J - F	Washington
Noridian Healthcare Solutions, LLC	A and B MAC	02402 - MAC B	J - F	Washington
Noridian Healthcare Solutions, LLC	A and B MAC	03101 - MAC A	J - F	Arizona
Noridian Healthcare Solutions, LLC	A and B MAC	03102 - MAC B	J - F	Arizona
Noridian Healthcare Solutions, LLC	A and B MAC	03201 - MAC A	J - F	Montana
Noridian Healthcare Solutions, LLC	A and B MAC	03202 - MAC B	J - F	Montana
Noridian Healthcare Solutions, LLC	A and B MAC	03301 - MAC A	J - F	North Dakota
Noridian Healthcare Solutions, LLC	A and B MAC	03302 - MAC B	J - F	North Dakota
Noridian Healthcare Solutions, LLC	A and B MAC	03401 - MAC A	J - F	South Dakota
Noridian Healthcare Solutions, LLC	A and B MAC	03402 - MAC B	J - F	South Dakota
Noridian Healthcare Solutions, LLC	A and B MAC	03501 - MAC A	J - F	Utah
Noridian Healthcare Solutions, LLC	A and B MAC	03502 - MAC B	J - F	Utah
Noridian Healthcare Solutions, LLC	A and B MAC	03601 - MAC A	J - F	Wyoming
Noridian Healthcare Solutions, LLC	A and B MAC	03602 - MAC B	J - F	Wyoming

LCD Information

Document Information

LCD ID

L38353

LCD Title

MolDX: Repeat Germline Testing

AMA CPT / ADA CDT / AHA NUBC Copyright Statement

Proposed LCD in Comment Period
N/A

Source Proposed LCD
DL38353

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N/A

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08/02/2020

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 others[1]. 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 individual[2]. 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 conditions[3-7]. 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.

Revision History Information

N/A

Associated Documents

Attachments

N/A

Related Local Coverage Documents

Articles

A57332 - Billing and Coding: MolDX: Repeat Germline Testing

A58177 - Response to Comments: MolDX: Repeat Germline Testing

LCDs

DL38353 - (MCD Archive Site)

Related National Coverage Documents

N/A

Public Versions

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