

LCD - MoIDX: HLA-DQB1*06:02 Testing for Narcolepsy (L36544)

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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
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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

L36544

LCD Title

MoIDX: HLA-DQB1*06:02 Testing for Narcolepsy

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Proposed LCD in Comment Period

N/A

Source Proposed LCD

[DL36544](#)

Original Effective Date

For services performed on or after 09/15/2016

Revision Effective Date

For services performed on or after 07/08/2021

Revision Ending Date

N/A

Retirement Date

N/A

Notice Period Start Date

07/28/2016

Notice Period End Date

09/30/2016

CMS National Coverage Policy

Title XVIII of the Social Security Act (SSA), §1862(a)(1)(A), states that no Medicare payment shall be made for items or services that "are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member."

CMS Internet-Only Manual, Pub. 100-02, Medicare Benefit Policy Manual, Chapter 15, §80 Requirements for Diagnostic X-Ray, Diagnostic Laboratory, and Other Diagnostic Tests

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

Coverage Guidance**Coverage Indications, Limitations, and/or Medical Necessity****Indications and Limitations of Coverage**

Based upon currently available information, HLA-DQB1*06:02 typing (81383) for the diagnosis or management of narcolepsy is considered experimental/investigational/unproven for all populations. Although research suggests a strong association between HLA-DQB1*06:02 and narcolepsy risk, HLA-DQB1*06:02 typing is insufficient to confirm a diagnosis of narcolepsy, rule out a diagnosis of narcolepsy or quantify risk for narcolepsy. Therefore, at this time there is no clinical utility for genetic testing or HLA-DQB1*06:02 typing in the diagnosis or treatment of narcolepsy.

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Background

Narcolepsy is a sleep disorder characterized by excessive daytime sleepiness, cataplexy (sudden loss of voluntary muscle tone), and uncontrollable sleep episodes. Most cases of narcolepsy are sporadic, with symptoms beginning around the time of adolescence.

According to the International Classification of Sleep Disorders, Third Edition (ICSD-3) and the Diagnostic and Statistical Manual of Mental Disorder, Fifth Edition (DSM-5), narcolepsy is diagnosed by a combination of physical exam, medical history, polysomnogram, multiple sleep latency testing (MSLT), and low CSF hypocretin-1 levels. Current recommended treatment options include stimulants and antidepressants. At this time, treatment is aimed towards the control of symptoms and is not curative.¹²

Narcolepsy has a multifactorial etiology, likely caused by the interaction between genetic risk factors and environmental exposures. Research efforts to identify the genetic contributors to narcolepsy have focused on an association between certain human leukocyte antigen (HLA) haplotypes and narcolepsy risk. The HLA complex encodes greater than 200 genes responsible for the recognition of foreign antigens. These genes are highly polymorphic, and certain alleles have long been known to confer risk for autoimmune disorders.

A variation of the HLA-DQB1 gene called HLA-DQB1*06:02 has been strongly associated with narcolepsy, particularly in individuals who also have cataplexy and a loss of hypocretins. Several genetic association studies in ethnically diverse populations have found a robust association between narcolepsy and the HLA-DQB1*06:02 allele. However, 15 to 25% of unaffected individuals in the general population also carry this risk haplotype, suggesting that it is necessary but not sufficient for the development of narcolepsy.⁶ Additionally, persons with narcolepsy and cataplexy have been identified without the HLA-DQB1*06:02 marker.⁴ More recent studies further suggest that predisposition to narcolepsy may be the result of complex genetic associations between multiple risk alleles.¹¹

Despite multiple studies replicating the association between HLA-DQB1*06:02 and narcolepsy in different ethnic groups, the overall contribution of HLA variation to disease risk is low. Monozygotic twin studies have shown only partial concordance (25-31%), indicating that environmental factors play a large role in the etiology of narcolepsy.⁸ Recent studies have suggested that exposure to streptococcus, H1N1, and the H1N1 vaccine may also increase the risk for narcolepsy, specifically among individuals with the HLA-DQB1*06:02 allele.^{3,14,4}

Although research suggests a strong association between HLA-DQB1*06:02 and narcolepsy risk, at this time there is no evidence for any diagnostic utility of HLA typing.⁵

Summary of Evidence

N/A

Analysis of Evidence (Rationale for Determination)

N/A

General Information

Associated Information

N/A

Sources of Information

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Bibliography

N/A

Revision History Information

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASONS FOR CHANGE
07/08/2021	R4	<p>Under CMS National Coverage Policy added regulation CMS Internet-Only Manual, Pub. 100-02, Medicare Benefit Policy Manual, Chapter 15, §80 Requirements for Diagnostic X-Ray, Diagnostic Laboratory, and Other Diagnostic Tests.</p> <p>Under Sources of Information moved citations to bibliography. Under Bibliography changes were made to citations to reflect AMA citation guidelines.</p>	<ul style="list-style-type: none"> • Provider Education/Guidance
11/01/2019	R3	<p>The LCD is revised to remove CPT/HCPCS codes in the Keyword Section of the LCD.</p> <p>At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; and, therefore not all the fields included on the LCD are applicable as noted in this policy.</p>	<ul style="list-style-type: none"> • Other (The LCD is revised to remove CPT/HCPCS codes in the Keyword Section of the LCD.)
11/01/2019	R2	<p>As required by CR 10901, all billing and coding information has been moved to the companion article, this article is linked to the LCD.</p> <p>At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; and, therefore not all the fields included on the LCD are applicable as noted in this policy.</p>	<ul style="list-style-type: none"> • Revisions Due To Code Removal
10/01/2016	R1	<p>LCD is revised to change effective date from 9/15/16 to 10/01/16. Although the LCD was publicly viewable on the MCD, Noridian did not post notice of the LCD finalizing until August 11, 2016.</p>	<ul style="list-style-type: none"> • Other (45 day notice of final LCD published to NHS website August 11, 2016.)

Associated Documents

Attachments

N/A

Related Local Coverage Documents

Articles

[A57465 - Billing and Coding: MoIDX: HLA-DQB1*06:02 Testing for Narcolepsy](#)

LCDs

[DL36544 - \(MCD Archive Site\)](#)

Related National Coverage Documents

N/A

Public Versions

UPDATED ON	EFFECTIVE DATES	STATUS
07/08/2021	07/08/2021 - N/A	Currently in Effect (This Version)
01/29/2020	11/01/2019 - 07/07/2021	Superseded
10/09/2019	11/01/2019 - N/A	Superseded

Some older versions have been archived. Please visit the MCD Archive Site to retrieve them.

Keywords

N/A