

Local Coverage Determination (LCD): MoIDX: HLA-DQB1*06:02 Testing for Narcolepsy (L36551)

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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

L36551

For services performed on or after 09/15/2016

LCD Title

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

Revision Effective Date

For services performed on or after 11/01/2019

Proposed LCD in Comment Period

N/A

Revision Ending Date

N/A

Source Proposed LCD

DL36551

Retirement Date

N/A

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Notice Period Start Date

07/28/2016

Notice Period End Date

09/30/2016

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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.”

Title XVIII of the Social Security Act, §1833(e), prohibits Medicare payment for any claim lacking the necessary documentation to process the claim.

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

CMS Internet Online Manual Pub. 100-02 (Medicare Benefit Policy Manual), Chapter 15, Section 80, “Requirements for Diagnostic X-Ray, Diagnostic Laboratory, and Other Diagnostic Tests”

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

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.

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	REASON(S) FOR CHANGE
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</p>	<ul style="list-style-type: none">• Revisions Due To Code Removal

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
		this policy.	
10/01/2016	R1	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.	<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

Article(s)

A57441 - Billing and Coding: MoIDX: HLA-DQB1*06:02 Testing for Narcolepsy

LCD(s)

DL36551

- (MCD Archive Site)

Related National Coverage Documents

N/A

Public Version(s)

Updated on 01/29/2020 with effective dates 11/01/2019 - N/A

Updated on 10/09/2019 with effective dates 11/01/2019 - N/A

Updated on 08/03/2016 with effective dates 10/01/2016 - 10/31/2019

Updated on 07/13/2016 with effective dates 09/15/2016 - N/A

Keywords

N/A