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

Noridian Healthcare Solutions, LLC

Please Note: This is a Proposed LCD.
Proposed LCDs are works in progress and not necessarily a reflection of the current policies or practices. Proposed LCDs in an approval status display on the CMS MCD for public review.

Contractor Information

Contractor Name Noridian Healthcare Solutions, LLC
Contract Number 01112
Contract Type A and B MAC

Proposed LCD Information

Source LCD ID N/A
Proposed LCD ID DL36551
Proposed LCD Title

MolDX- HLA-DQB1*06-02 Testing for Narcolepsy

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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.

CMS National Coverage Policy

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.
Jurisdiction
California - Northern
Super MAC Jurisdiction
J - E

Coverage Guidance

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.

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. Additionally, persons with narcolepsy and cataplexy have been identified without the HLA-DQB1*06:02 marker. More recent studies further suggest that predisposition to narcolepsy may be the result of complex genetic associations between multiple risk alleles.

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. 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.

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.

### Proposed Process Information

**Synopsis of Changes**

**Fields Changed**

Not Applicable

**Associated Information**

**Sources of Information and Basis for Decision**


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Open Meetings

Part B MAC Contractor Advisory Committee (CAC) Meetings

Comment Period Start Date 02/04/2016

Comment Period End Date 04/10/2016

Released to Final LCD Date Not yet released.

Reason for Proposed LCD Creation of Uniform LCDs...

Reason for Proposed LCD Creation of Uniform LCDs With Other MAC Jurisdiction

Proposed LCD Contact Noridian Healthcare Solutions, LLC JE Part B Contractor Medical Director(s)

Proposed LCD Contact Attention: Draft LCD Comments PO Box 6783 Fargo, North Dakota 58108-6783 policyb.drafts@noridian.com

Coding Information
Bill Type Codes

Revenue Codes

CPT/HCPCS Codes

Group 1: Paragraph
N/A

Group 1: Codes
81383

HLA CLASS II TYPING, HIGH RESOLUTION (IE, ALLELES OR ALLELE GROUPS); ONE ALLELE OR ALLELE GROUP (EG, HLA-DQB1*06:02P), EACH

Does the CPT 30% Coding Rule Apply?
No

ICD-10 Codes that Support Medical Necessity

Group 1: Paragraph
N/A

Group 1: Codes
G47.411 Narcolepsy with cataplexy
G47.419 Narcolepsy without cataplexy
G47.421 Narcolepsy in conditions classified elsewhere with cataplexy

Note: Performance is optimized by using code ranges.

ICD-10 Codes that DO NOT Support Medical Necessity

Group 1: Paragraph

Group 1: Codes

Note: Performance is optimized by using code ranges.

Additional ICD-10 Information

Associated Documents

There are no attachments for this LCD.
This LCD version has no Related Local Coverage Documents.
This LCD version has no Related National Coverage Documents.