

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

CGS Administrators, LLC

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**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	
	
<b>Contractor Name</b>	CGS Administrators, LLC
<b>Contract Number</b>	15102
<b>Contract Type</b>	MAC - Part B
<b>Associated Contract Numbers</b>	(MAC - Part B - 15202) CGS Administrators, LLC, (MAC - Part A - 15101) CGS Administrators, LLC, (MAC - Part A - 15201) CGS Administrators, LLC

Proposed LCD Information	
	
<b>Source LCD ID</b>	N/A
<b>Proposed LCD ID</b>	DL36485

<b>Original ICD-9 LCD ID</b>	N/A
<b>Proposed LCD Version</b>	2
<b>Proposed LCD Title</b>	<b>MoIDX: HLA-DQB1*06:02 Testing for Narcolepsy</b>
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<b>CMS National Coverage Policy</b>	<p>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."</p> <p>Title XVIII of the Social Security Act, §1833(e), prohibits Medicare payment for any claim lacking the necessary documentation to process the claim.</p> <p>42 Code of Federal Regulations (CFR) §410.32 Diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic</p>

	<p>tests: Conditions.</p> <p>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"</p> <p>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.</p> <p>CMS Internet Online Manual Pub. 100-04 (Medicare Claims Processing Manual), Chapter 23 (Section 10) "Reporting ICD Diagnosis and Procedure Codes"</p>
<b>Jurisdiction</b>	Kentucky

**Coverage Guidance**



<p><b>Coverage Indications, Limitations and/or Medical Necessity</b></p>	<p><b>Indications and Limitations of Coverage</b></p> <p>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.</p> <p><b>Background</b></p> <p>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</p>
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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.<sup>12</sup>

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.<sup>6</sup> Additionally, persons with narcolepsy and cataplexy have been identified without the HLA-DQB1\*06:02 marker.<sup>4</sup> More recent studies further suggest that predisposition to narcolepsy may be the result of complex genetic associations between multiple risk alleles.<sup>11</sup>

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.<sup>8</sup> Recent studies have suggested that exposure to streptococcus, H1N1, and the

	<p>H1N1 vaccine may also increase the risk for narcolepsy, specifically among individuals with the HLA-DQB1*06:02 allele.<sup>3,14,4</sup></p> <p>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.<sup>5</sup></p>
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### Proposed Process Information



#### Associated Information

#### Sources of Information and Basis for Decision

1. American Academy of Sleep Medicine. The International Classification of Sleep Disorders. 2014.3rd ed.
2. American Psychiatric Association. Diagnostic and statistical manual of mental disorders (5th ed.). Arlington, VA: American Psychiatric Publishing. 2013.
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388 only, 2011.

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15. Tafti M, Hor H, Dauvilliers Y, et al. DQB1 locus alone explains most of the risk and protection in narcolepsy with cataplexy in Europe. Sleep. 2014. 37:19–25.

**Open Meetings**

**Meeting Date**

**Meeting Information**

**State**

**Part B MAC Contractor Advisory Committee (CAC)**

**Meeting Date**

**Meeting Information**

**State**

10/19/2015

This policy will be presented at the

Kentucky


<b>Meetings</b>		Kentucky CAC meeting October 19, 2015.	
	10/20/2015	This policy will be presented at the Ohio CAC meeting October 20, 2015.	Ohio
<b>Comment Period Start Date</b>	10/21/2015		
<b>Comment Period End Date</b>	12/07/2015		
<b>Released to Final LCD Date</b>	Not yet released.		
<b>Reason for Proposed LCD</b>	Provider Education/Guidance		
<b>Proposed LCD Contact</b>	Earl Berman, MD Attn Medical Review Two Vantage Way Nashville, Tennessee 37228- <a href="mailto:cmd.inquiry@cgsadmin.com">cmd.inquiry@cgsadmin.com</a>		

**Coding Information**



<b>Bill Type Codes</b>			
<b>Revenue Codes</b>			
<b>CPT/HCPCS Codes</b>	<p><b>Group 1: Paragraph</b> N/A</p> <p><b>Group 1: Codes</b></p> <table border="1"> <tr> <td>81383</td> <td>HLA CLASS II TYPING, HIGH RESOLUTION (IE, ALLELES OR ALLELE GROUPS); ONE ALLELE OR ALLELE GROUP (EG, HLA-DQB1*06:02P), EACH</td> </tr> </table>	81383	HLA CLASS II TYPING, HIGH RESOLUTION (IE, ALLELES OR ALLELE GROUPS); ONE ALLELE OR ALLELE GROUP (EG, HLA-DQB1*06:02P), EACH
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<b>Does the CPT 30% Coding Rule Apply?</b>	No		

<p><b>ICD-10 Codes that Support Medical Necessity</b></p> <p><b>Note: Performance is optimized by using code ranges.</b></p>	<p><b>Group 1: Paragraph</b> N/A</p> <p><b>Group 1: Codes</b></p> <table border="1"> <tr> <td>G47.411</td> <td>Narcolepsy with cataplexy</td> </tr> <tr> <td>G47.419</td> <td>Narcolepsy without cataplexy</td> </tr> <tr> <td>G47.421</td> <td>Narcolepsy in conditions classified elsewhere with cataplexy</td> </tr> </table>	G47.411	Narcolepsy with cataplexy	G47.419	Narcolepsy without cataplexy	G47.421	Narcolepsy in conditions classified elsewhere with cataplexy
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G47.421	Narcolepsy in conditions classified elsewhere with cataplexy						
<p><b>ICD-10 Codes that DO NOT Support Medical Necessity</b></p> <p><b>Note: Performance is optimized by using code ranges.</b></p>	<p><b>Group 1: Paragraph</b></p> <p><b>Group 1: Codes</b></p> <table border="1"> <tr> <td> </td> <td> </td> </tr> </table>						
<p><b>Additional ICD-10 Information</b></p>							

<p><b>Associated Documents</b></p>	
<div style="text-align: center;">  </div>	
<p><b>Attachments</b></p>	<p>There are no attachments for this LCD.</p>
<p><b>Related Local Coverage Documents</b></p>	<p>This LCD version has no Related Local Coverage Documents.</p>
<p><b>Related National Coverage Documents</b></p>	<p>This LCD version has no Related National Coverage Documents.</p>
<p><b>All Versions</b></p>	<p><b>Version 2 - Updated on 09/23/2015 08:24:29, by <a href="mailto:derita.wardell@cgsadmin.com">derita.wardell@cgsadmin.com</a>, with effective dates N/A - N/A (Approved).</b></p> <p><a href="#">Version 1</a> - Updated on 09/23/2015 08:18:39, by <a href="mailto:derita.wardell@cgsadmin.com">derita.wardell@cgsadmin.com</a>, with effective dates N/A - N/A.</p>



**Additional Information**



**Contractor Only  
Notes**

**Keywords**

**Saved By**

derita.wardell@cgsadmin.com

**Saved On**

09/23/2015

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