

# Local Coverage Determination (LCD): MoIDX: HLA-B\*15:02 Genetic Testing (L36145)

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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

L36145

For services performed on or after 04/01/2016

**LCD Title**

MoIDX: HLA-B\*15:02 Genetic Testing

**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**

DL36145

**Retirement Date**

N/A

**AMA CPT / ADA CDT / AHA NUBC Copyright Statement**

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**Notice Period Start Date**

02/11/2016

**Notice Period End Date**

03/31/2016

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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.”

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

This policy provides limited coverage for HLA-B\*15:02 genotype testing when the following criteria are met:

- Patient is of Asian and Oceanian ancestry; **AND**
- Initial treatment with carbamazepine, phenytoin or fosphenytoin is planned

#### Background

In 2004, researchers reported individuals with the HLA-B\*1502 had an increased risk to develop Stevens-Johnson syndrome (SJS) or toxic epidermal necrolysis (TEN) when exposed to carbamazepine<sup>2</sup>. SJS and TEN, considered two variants of a disease continuum, are severe, sometimes lethal diseases of the skin and mucous membranes. A third, intermediate condition is called SJS/TEN. The most serious cases result in separation of the epidermis from the dermis in large sheets, which can also lead to infection. Sloughing can also occur in the bronchial, gastrointestinal and ocular epithelia.

Estimates indicate 10-15% of the population from China, Thailand, Malaysia, Indonesia, the Philippines, and Taiwan carry the HLA-B\*1502 allele. South Asians, including Indians, appear to have an intermediate chance of having HLA-B\*1502, averaging 2 to 4%, but it is higher in some subgroups. Oceanians also have an increased incidence of HLA-B\*1502 serotype. The incidence of the HLA-B\*1502 serotype in the European Caucasian population has been reported at less than 0.1% <sup>1</sup>, in the African population as 0.2% and in the Native American and Hispanic populations as 0% <sup>3</sup>.

In 2007, the FDA issued a black box label warning for carbamazepine stating, “Patients with ancestry in genetically at-risk populations should be screened for the presence of HLA-B\*1502 prior to initiating treatment.” More recent evidence has supported the FDA recommendations <sup>4</sup> and at least one study has demonstrated that prospective screening of HLA-B\*1502 has reduced the incidence of SJS/TEN in a Chinese population <sup>5</sup>.

#### Summary of Evidence

N/A

#### Analysis of Evidence (Rationale for Determination)

N/A

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## General Information

### Associated Information

### Documentation Requirements

The patient's medical record must contain documentation that fully supports the medical necessity for services included within this LCD. (see "**Coverage Indications, Limitations, and/or Medical Necessity**"). This documentation includes, but is not limited to, relevant medical history, physical examination, and results of pertinent diagnostic tests or procedures.

Documentation supporting the medical necessity should be legible, maintained in the patient's medical record, and must be made available to the MAC upon request.

### Sources of Information

N/A

### Bibliography

1. Aihara, M. Pharmacogenomics of cutaneous adverse drug reactions. *J Dermatol.* 2011;38:246-54.
2. Chen, P. et al.; Taiwan SJS Consortium. Carbamazepine-induced toxic effects and HLA-B\*1502 screening in Taiwan. *N. Engl. J. Med.* 2011;364, 1126-1133.
3. Chung WH, Hung SI, Hong HS, et al. Medical genetics: a marker for Stevens-Johnson syndrome. *Nature.* 2004;428:486.
4. Miller JW. Of race, ethnicity, and rash: the genetics of antiepileptic drug-induced skin reactions. *Epilepsy Curr.* 2008 Sep-Oct;8(5):120-1.
5. Tangamornsuksan W, Chaiyakunapruk N, Somkrua R, et al. Relationship between the HLA-B\*1502 allele and carbamazepine-induced Stevens-Johnson syndrome and toxic epidermal necrolysis: a systematic review and meta-analysis. *JAMA Dermatol.* 2013 Sep;149(9):1025-32.

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## Revision History Information

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
11/01/2019	R4	The LCD is revised to remove CPT/HCPCS codes in the Keyword Section of the LCD.	<ul style="list-style-type: none"><li>• Other (The LCD is revised to remove CPT/HCPCS codes in the Keyword Section of the LCD.</li></ul>

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
		<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>	)
11/01/2019	R3	<p>11/01/2019: This LCD is being revised in order to adhere to CMS requirements per chapter 13, section 13.5.1 of the Program Integrity Manual, to remove all coding from LCDs. There has been no change in coverage with this LCD revision.</p> <p>Regulations regarding billing and coding were removed from the <b>CMS National Coverage Policy</b> section of this LCD and placed in the related Billing and Coding: MoIDX: HLA-B*15:02 Genetic Testing A57466 article.</p> <p>Under <b>Sources of Information</b> references were moved to the <b>Bibliography</b> section. Punctuation and typographical errors were corrected throughout the article.</p> <p><i>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</i></p>	<ul style="list-style-type: none"> <li>• Provider Education/Guidance</li> </ul>
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"> <li>• Revisions Due To Code Removal</li> </ul>
02/26/2018	R1	05/23/2019: At this time 21st Century Cures	<ul style="list-style-type: none"> <li>• Creation of Uniform LCDs With Other MAC Jurisdiction</li> </ul>

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
		<p>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> <p>Added ICD-10 B20 to the list of payable diagnosis codes.</p>	<ul style="list-style-type: none"> <li>Revisions Due To ICD-10-CM Code Changes</li> </ul>

## Associated Documents

### Attachments

N/A

### Related Local Coverage Documents

Article(s)

A57466 - Billing and Coding: MoIDX: HLA-B\*15:02 Genetic Testing

A54874 - Response to Comments: MoIDX: HLA-B\*15:02 Genetic Testing

LCD(s)

DL36100

- (MCD Archive Site)DL36145

- (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 12/04/2019 with effective dates 11/01/2019 - N/A

Updated on 10/08/2019 with effective dates 11/01/2019 - N/A

Updated on 05/28/2019 with effective dates 02/26/2018 - 10/31/2019

Updated on 01/29/2016 with effective dates 04/01/2016 - N/A

## Keywords

N/A