Local Coverage Determination (LCD):
MolDX: HLA-B*15:02 Genetic Testing (L36801)

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Contractor Information

Contractor Name	Contract Type	Contract Number	Jurisdiction	State(s)
Wisconsin Physicians Service Insurance Corporation	MAC - Part A	05101 - MAC A	J - 05	Iowa
Wisconsin Physicians Service Insurance Corporation	MAC - Part B	05102 - MAC B	J - 05	Iowa
Wisconsin Physicians Service Insurance Corporation	MAC - Part A	05201 - MAC A	J - 05	Kansas
Wisconsin Physicians Service Insurance Corporation	MAC - Part B	05202 - MAC B	J - 05	Kansas
Wisconsin Physicians Service Insurance Corporation	MAC - Part A	05301 - MAC A	J - 05	Missouri - Entire State
Wisconsin Physicians Service Insurance Corporation	MAC - Part B	05302 - MAC B	J - 05	Missouri - Entire State
Wisconsin Physicians Service Insurance Corporation	MAC - Part A	05401 - MAC A	J - 05	Nebraska
Wisconsin Physicians Service Insurance Corporation	MAC - Part B	05402 - MAC B	J - 05	Nebraska
Wisconsin Physicians Service Insurance Corporation	MAC - Part A	05901 - MAC A	J - 05	Alaska Alabama Arkansas Arizona Connecticut Florida Georgia Iowa Idaho Illinois Indiana Kansas Kentucky Louisiana Massachusetts Maine Michigan Minnesota Missouri - Entire State Mississippi Montana North Carolina North Dakota Nebraska New Hampshire New Jersey Ohio Oregon Rhode Island South Carolina South Dakota Tennessee Utah

Contractor Name	Contract Type	Contract Number	Jurisdiction	State(s)
				Virginia Virgin Islands Vermont Washington Wisconsin West Virginia Wyoming
Wisconsin Physicians Service Insurance Corporation	MAC - Part A	08101 - MAC A	J - 08	Indiana
Wisconsin Physicians Service Insurance Corporation	MAC - Part B	08102 - MAC B	J - 08	Indiana
Wisconsin Physicians Service Insurance Corporation	MAC - Part A	08201 - MAC A	J - 08	Michigan
Wisconsin Physicians Service Insurance Corporation	MAC - Part B	08202 - MAC B	J - 08	Michigan

Back to Top

LCD Information

Document Information

LCD ID
L36801

LCD Title
MolDX: HLA-B*15:02 Genetic Testing

Proposed LCD in Comment Period
N/A

Source Proposed LCD
N/A

Original Effective Date
For services performed on or after 02/16/2017

Revision Effective Date
For services performed on or after 01/01/2018

Revision Ending Date
N/A

Retirement Date
N/A

Notice Period Start Date
01/01/2017

Notice Period End Date
02/15/2017

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"

CMS Internet-Only Manual, Pub 100-04, Medicare Claims Processing Manual, Chapter 12, §30-Correct Coding Policy

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 (SIS) or toxic epidermal necrolysis (TEN) when exposed to carbamazepine[2]. 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% [1], in the African population as 0.2% and in the Native American and Hispanic populations as 0% [3] .

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 [4] 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 [5].

Summary of Evidence

NA

Analysis of Evidence
(Rationale for Determination)

NA

Back to Top

Coding Information

Bill Type Codes:

Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the policy does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally to all claims.

N/A
Revenue Codes:

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory. Unless specified in the policy, services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally to all Revenue Codes.

N/A
CPT/HCPCS Codes
Group 1 Paragraph: N/A

Group 1 Codes:

81381	HLA CLASS I TYPING, HIGH RESOLUTION (IE, ALLELES OR ALLELE GROUPS); ONE ALLELE OR ALLELE GROUP (EG, B*57:01P), EACH

ICD-10 Codes that Support Medical Necessity
Group 1 Paragraph: N/A

Group 1 Codes:

ICD-10 Codes	Description
B02.22	Postherpetic trigeminal neuralgia
F31.0	Bipolar disorder, current episode hypomanic
F31.10	Bipolar disorder, current episode manic without psychotic features, unspecified
F31.11	Bipolar disorder, current episode manic without psychotic features, mild
F31.12	Bipolar disorder, current episode manic without psychotic features, moderate
F31.13	Bipolar disorder, current episode manic without psychotic features, severe
F31.2	Bipolar disorder, current episode manic severe with psychotic features
F31.30	Bipolar disorder, current episode depressed, mild or moderate severity, unspecified
F31.31	Bipolar disorder, current episode depressed, mild
F31.32	Bipolar disorder, current episode depressed, moderate

ICD-10 Codes	Description
F31.4	Bipolar disorder, current episode depressed, severe, without psychotic features
F31.5	Bipolar disorder, current episode depressed, severe, with psychotic features
F31.60	Bipolar disorder, current episode mixed, unspecified
F31.61	Bipolar disorder, current episode mixed, mild
F31.62	Bipolar disorder, current episode mixed, moderate
F31.63	Bipolar disorder, current episode mixed, severe, without psychotic features
F31.64	Bipolar disorder, current episode mixed, severe, with psychotic features
F31.70	Bipolar disorder, currently in remission, most recent episode unspecified
F31.71	Bipolar disorder, in partial remission, most recent episode hypomanic
F31.72	Bipolar disorder, in full remission, most recent episode hypomanic
F31.73	Bipolar disorder, in partial remission, most recent episode manic
F31.74	Bipolar disorder, in full remission, most recent episode manic
F31.75	Bipolar disorder, in partial remission, most recent episode depressed
F31.76	Bipolar disorder, in full remission, most recent episode depressed
F31.77	Bipolar disorder, in partial remission, most recent episode mixed
F31.78	Bipolar disorder, in full remission, most recent episode mixed
F31.81	Bipolar II disorder
F31.89	Other bipolar disorder
F31.9	Bipolar disorder, unspecified
G40.001	Localization-related (focal) (partial) idiopathic epilepsy and epileptic syndromes with seizures of localized onset, not intractable, with status epilepticus
G40.009	Localization-related (focal) (partial) idiopathic epilepsy and epileptic syndromes with seizures of localized onset, not intractable, without status epilepticus
G40.011	Localization-related (focal) (partial) idiopathic epilepsy and epileptic syndromes with seizures of localized onset, intractable, with status epilepticus
G40.019	Localization-related (focal) (partial) idiopathic epilepsy and epileptic syndromes with seizures of localized onset, intractable, without status epilepticus
G40.101	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with simple partial seizures, not intractable, with status epilepticus
G40.109	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with simple partial seizures, not intractable, without status epilepticus
G40.111	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with simple partial seizures, intractable, with status epilepticus
G40.119	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with simple partial seizures, intractable, without status epilepticus
G40.201	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with complex partial seizures, not intractable, with status epilepticus
G40.209	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with complex partial seizures, not intractable, without status epilepticus
G40.211	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with complex partial seizures, intractable, with status epilepticus
G40.219	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with complex partial seizures, intractable, without status epilepticus
G40.301	Generalized idiopathic epilepsy and epileptic syndromes, not intractable, with status epilepticus
G40.309	Generalized idiopathic epilepsy and epileptic syndromes, not intractable, without status epilepticus
G40.311	Generalized idiopathic epilepsy and epileptic syndromes, intractable, with status epilepticus
G40.319	Generalized idiopathic epilepsy and epileptic syndromes, intractable, without status epilepticus
G40.401	Other generalized epilepsy and epileptic syndromes, not intractable, with status epilepticus
G40.409	Other generalized epilepsy and epileptic syndromes, not intractable, without status epilepticus
G40.411	Other generalized epilepsy and epileptic syndromes, intractable, with status epilepticus
G40.419	Other generalized epilepsy and epileptic syndromes, intractable, without status epilepticus
G40.501	Epileptic seizures related to external causes, not intractable, with status epilepticus
G40.509	Epileptic seizures related to external causes, not intractable, without status epilepticus
G40.801	Other epilepsy, not intractable, with status epilepticus
G40.802	Other epilepsy, not intractable, without status epilepticus
G40.803	Other epilepsy, intractable, with status epilepticus
G40.804	Other epilepsy, intractable, without status epilepticus
G40.811	Lennox-Gastaut syndrome, not intractable, with status epilepticus
G40.812	Lennox-Gastaut syndrome, not intractable, without status epilepticus

ICD-10 Codes	Description
G40.813	Lennox-Gastaut syndrome, intractable, with status epilepticus
G40.814	Lennox-Gastaut syndrome, intractable, without status epilepticus
G40.821	Epileptic spasms, not intractable, with status epilepticus
G40.822	Epileptic spasms, not intractable, without status epilepticus
G40.823	Epileptic spasms, intractable, with status epilepticus
G40.824	Epileptic spasms, intractable, without status epilepticus
G40.89	Other seizures
G40.901	Epilepsy, unspecified, not intractable, with status epilepticus
G40.909	Epilepsy, unspecified, not intractable, without status epilepticus
G40.911	Epilepsy, unspecified, intractable, with status epilepticus
G40.919	Epilepsy, unspecified, intractable, without status epilepticus
G50.0	Trigeminal neuralgia
G52.1	Disorders of glossopharyngeal nerve
Z17.0	Estrogen receptor positive status [ER+]
Z94.0	Kidney transplant status
Z94.1	Heart transplant status
Z94.2	Lung transplant status
Z94.3	Heart and lungs transplant status
Z94.4	Liver transplant status
Z94.81	Bone marrow transplant status
Z94.82	Intestine transplant status
Z94.83	Pancreas transplant status
Z94.84	Stem cells transplant status

ICD-10 Codes that DO NOT Support Medical Necessity
Group 1 Paragraph: NA

Group 1 Codes: N/A

ICD-10 Additional Information Back to Top

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.

Back to Top

Revision History Information

Revision History Date	Revision History Number	Revision History Explanation	Reason(s) for Change
01/01/2018	R1	01/01/2018: Annual Review completed 11/27/2017. 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.	• Other (Annual Review)

Back to Top

Associated Documents

Attachments N/A

Related Local Coverage Documents Article(s) A55380 - Response to Comments: MolDX: HLA-B*15:02 Genetic Testing (L36801)

Related National Coverage Documents N/A

Public Version(s) Updated on 12/18/2017 with effective dates 01/01/2018 - N/A Updated on 12/19/2016 with effective dates 02/16/2017 - N/A Back to Top

Keywords

N/A Read the **LCD Disclaimer** Back to Top