## Contractor Information

<table>
<thead>
<tr>
<th>Contractor Name</th>
<th>Contract Type</th>
<th>Contract Number</th>
<th>Jurisdiction</th>
<th>State(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Noridian Healthcare Solutions, LLC</td>
<td>A and B MAC</td>
<td>02101 - MAC A</td>
<td>J - F</td>
<td>Alaska</td>
</tr>
<tr>
<td>Noridian Healthcare Solutions, LLC</td>
<td>A and B MAC</td>
<td>02102 - MAC B</td>
<td>J - F</td>
<td>Alaska</td>
</tr>
<tr>
<td>Noridian Healthcare Solutions, LLC</td>
<td>A and B MAC</td>
<td>02201 - MAC A</td>
<td>J - F</td>
<td>Idaho</td>
</tr>
<tr>
<td>Noridian Healthcare Solutions, LLC</td>
<td>A and B MAC</td>
<td>02202 - MAC B</td>
<td>J - F</td>
<td>Idaho</td>
</tr>
<tr>
<td>Noridian Healthcare Solutions, LLC</td>
<td>A and B MAC</td>
<td>02301 - MAC A</td>
<td>J - F</td>
<td>Oregon</td>
</tr>
<tr>
<td>Noridian Healthcare Solutions, LLC</td>
<td>A and B MAC</td>
<td>02302 - MAC B</td>
<td>J - F</td>
<td>Oregon</td>
</tr>
<tr>
<td>Noridian Healthcare Solutions, LLC</td>
<td>A and B MAC</td>
<td>02401 - MAC A</td>
<td>J - F</td>
<td>Washington</td>
</tr>
<tr>
<td>Noridian Healthcare Solutions, LLC</td>
<td>A and B MAC</td>
<td>02402 - MAC B</td>
<td>J - F</td>
<td>Washington</td>
</tr>
<tr>
<td>Noridian Healthcare Solutions, LLC</td>
<td>A and B MAC</td>
<td>03101 - MAC A</td>
<td>J - F</td>
<td>Arizona</td>
</tr>
<tr>
<td>Noridian Healthcare Solutions, LLC</td>
<td>A and B MAC</td>
<td>03102 - MAC B</td>
<td>J - F</td>
<td>Arizona</td>
</tr>
<tr>
<td>Noridian Healthcare Solutions, LLC</td>
<td>A and B MAC</td>
<td>03201 - MAC A</td>
<td>J - F</td>
<td>Montana</td>
</tr>
<tr>
<td>Noridian Healthcare Solutions, LLC</td>
<td>A and B MAC</td>
<td>03202 - MAC B</td>
<td>J - F</td>
<td>Montana</td>
</tr>
<tr>
<td>Noridian Healthcare Solutions, LLC</td>
<td>A and B MAC</td>
<td>03301 - MAC A</td>
<td>J - F</td>
<td>North Dakota</td>
</tr>
<tr>
<td>Noridian Healthcare Solutions, LLC</td>
<td>A and B MAC</td>
<td>03302 - MAC B</td>
<td>J - F</td>
<td>North Dakota</td>
</tr>
<tr>
<td>Noridian Healthcare Solutions, LLC</td>
<td>A and B MAC</td>
<td>03401 - MAC A</td>
<td>J - F</td>
<td>South Dakota</td>
</tr>
<tr>
<td>Noridian Healthcare Solutions, LLC</td>
<td>A and B MAC</td>
<td>03402 - MAC B</td>
<td>J - F</td>
<td>South Dakota</td>
</tr>
<tr>
<td>Noridian Healthcare Solutions, LLC</td>
<td>A and B MAC</td>
<td>03501 - MAC A</td>
<td>J - F</td>
<td>Utah</td>
</tr>
<tr>
<td>Noridian Healthcare Solutions, LLC</td>
<td>A and B MAC</td>
<td>03502 - MAC B</td>
<td>J - F</td>
<td>Utah</td>
</tr>
<tr>
<td>Noridian Healthcare Solutions, LLC</td>
<td>A and B MAC</td>
<td>03601 - MAC A</td>
<td>J - F</td>
<td>Wyoming</td>
</tr>
<tr>
<td>Noridian Healthcare Solutions, LLC</td>
<td>A and B MAC</td>
<td>03602 - MAC B</td>
<td>J - F</td>
<td>Wyoming</td>
</tr>
</tbody>
</table>

## LCD Information

### Document Information

- **Original Effective Date**: For services performed on or after 04/01/2016
- **Revision Effective Date**: N/A
- **Revision Ending Date**: N/A
- **Retirement Date**: N/A
- **Notice Period Start Date**: 02/11/2016
- **Notice Period End Date**: 03/31/2016

---

**Contractor Name**: Noridian Healthcare Solutions, LLC

**Contract Type**: A and B MAC

**Contract Number**: 02101 - MAC A

**Jurisdiction**: Alaska

**State(s)**: Alaska

---

**Contractor Name**: Noridian Healthcare Solutions, LLC

**Contract Type**: A and B MAC

**Contract Number**: 02102 - MAC B

**Jurisdiction**: Alaska

**State(s)**: Alaska

---

**Contractor Name**: Noridian Healthcare Solutions, LLC

**Contract Type**: A and B MAC

**Contract Number**: 02201 - MAC A

**Jurisdiction**: Idaho

**State(s)**: Idaho

---

**Contractor Name**: Noridian Healthcare Solutions, LLC

**Contract Type**: A and B MAC

**Contract Number**: 02202 - MAC B

**Jurisdiction**: Idaho

**State(s)**: Idaho

---

**Contractor Name**: Noridian Healthcare Solutions, LLC

**Contract Type**: A and B MAC

**Contract Number**: 02301 - MAC A

**Jurisdiction**: Oregon

**State(s)**: Oregon

---

**Contractor Name**: Noridian Healthcare Solutions, LLC

**Contract Type**: A and B MAC

**Contract Number**: 02302 - MAC B

**Jurisdiction**: Oregon

**State(s)**: Oregon

---

**Contractor Name**: Noridian Healthcare Solutions, LLC

**Contract Type**: A and B MAC

**Contract Number**: 02401 - MAC A

**Jurisdiction**: Washington

**State(s)**: Washington

---

**Contractor Name**: Noridian Healthcare Solutions, LLC

**Contract Type**: A and B MAC

**Contract Number**: 02402 - MAC B

**Jurisdiction**: Washington

**State(s)**: Washington

---

**Contractor Name**: Noridian Healthcare Solutions, LLC

**Contract Type**: A and B MAC

**Contract Number**: 03101 - MAC A

**Jurisdiction**: Arizona

**State(s)**: Arizona

---

**Contractor Name**: Noridian Healthcare Solutions, LLC

**Contract Type**: A and B MAC

**Contract Number**: 03102 - MAC B

**Jurisdiction**: Arizona

**State(s)**: Arizona

---

**Contractor Name**: Noridian Healthcare Solutions, LLC

**Contract Type**: A and B MAC

**Contract Number**: 03201 - MAC A

**Jurisdiction**: Montana

**State(s)**: Montana

---

**Contractor Name**: Noridian Healthcare Solutions, LLC

**Contract Type**: A and B MAC

**Contract Number**: 03202 - MAC B

**Jurisdiction**: Montana

**State(s)**: Montana

---

**Contractor Name**: Noridian Healthcare Solutions, LLC

**Contract Type**: A and B MAC

**Contract Number**: 03301 - MAC A

**Jurisdiction**: North Dakota

**State(s)**: North Dakota

---

**Contractor Name**: Noridian Healthcare Solutions, LLC

**Contract Type**: A and B MAC

**Contract Number**: 03302 - MAC B

**Jurisdiction**: North Dakota

**State(s)**: North Dakota

---

**Contractor Name**: Noridian Healthcare Solutions, LLC

**Contract Type**: A and B MAC

**Contract Number**: 03401 - MAC A

**Jurisdiction**: South Dakota

**State(s)**: South Dakota

---

**Contractor Name**: Noridian Healthcare Solutions, LLC

**Contract Type**: A and B MAC

**Contract Number**: 03402 - MAC B

**Jurisdiction**: South Dakota

**State(s)**: South Dakota

---

**Contractor Name**: Noridian Healthcare Solutions, LLC

**Contract Type**: A and B MAC

**Contract Number**: 03501 - MAC A

**Jurisdiction**: Utah

**State(s)**: Utah

---

**Contractor Name**: Noridian Healthcare Solutions, LLC

**Contract Type**: A and B MAC

**Contract Number**: 03502 - MAC B

**Jurisdiction**: Utah

**State(s)**: Utah

---

**Contractor Name**: Noridian Healthcare Solutions, LLC

**Contract Type**: A and B MAC

**Contract Number**: 03601 - MAC A

**Jurisdiction**: Wyoming

**State(s)**: Wyoming

---

**Contractor Name**: Noridian Healthcare Solutions, LLC

**Contract Type**: A and B MAC

**Contract Number**: 03602 - MAC B

**Jurisdiction**: Wyoming

**State(s)**: Wyoming
• Patient is of Asian and Oceanian ancestry; AND

• Initial treatment with carbamazepine, phenytoin or fosphenytoin is planned

**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 allele had an increased risk to develop Stevens-Johnson syndrome (SJS) 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 \(^5\).

---

**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.

999x Not Applicable

**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:**

Printed on 4/21/2016. Page 3 of 6
<table>
<thead>
<tr>
<th>ICD-10 Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>B02.22</td>
<td>Postherpetic trigeminal neuralgia</td>
</tr>
<tr>
<td>F31.0</td>
<td>Bipolar disorder, current episode hypomanic</td>
</tr>
<tr>
<td>F31.10</td>
<td>Bipolar disorder, current episode manic without psychotic features, unspecified</td>
</tr>
<tr>
<td>F31.11</td>
<td>Bipolar disorder, current episode manic without psychotic features, mild</td>
</tr>
<tr>
<td>F31.12</td>
<td>Bipolar disorder, current episode manic without psychotic features, moderate</td>
</tr>
<tr>
<td>F31.13</td>
<td>Bipolar disorder, current episode manic without psychotic features, severe</td>
</tr>
<tr>
<td>F31.2</td>
<td>Bipolar disorder, current episode manic severe with psychotic features</td>
</tr>
<tr>
<td>F31.30</td>
<td>Bipolar disorder, current episode depressed, mild or moderate severity, unspecified</td>
</tr>
<tr>
<td>F31.31</td>
<td>Bipolar disorder, current episode depressed, mild</td>
</tr>
<tr>
<td>F31.32</td>
<td>Bipolar disorder, current episode depressed, moderate</td>
</tr>
<tr>
<td>F31.4</td>
<td>Bipolar disorder, current episode depressed, severe, without psychotic features</td>
</tr>
<tr>
<td>F31.5</td>
<td>Bipolar disorder, current episode depressed, severe, with psychotic features</td>
</tr>
<tr>
<td>F31.60</td>
<td>Bipolar disorder, current episode mixed, unspecified</td>
</tr>
<tr>
<td>F31.61</td>
<td>Bipolar disorder, current episode mixed, mild</td>
</tr>
<tr>
<td>F31.62</td>
<td>Bipolar disorder, current episode mixed, moderate</td>
</tr>
<tr>
<td>F31.63</td>
<td>Bipolar disorder, current episode mixed, severe, without psychotic features</td>
</tr>
<tr>
<td>F31.64</td>
<td>Bipolar disorder, current episode mixed, severe, with psychotic features</td>
</tr>
<tr>
<td>F31.70</td>
<td>Bipolar disorder, currently in remission, most recent episode unspecified</td>
</tr>
<tr>
<td>F31.71</td>
<td>Bipolar disorder, in partial remission, most recent episode hypomanic</td>
</tr>
<tr>
<td>F31.72</td>
<td>Bipolar disorder, in full remission, most recent episode hypomanic</td>
</tr>
<tr>
<td>F31.73</td>
<td>Bipolar disorder, in partial remission, most recent episode manic</td>
</tr>
<tr>
<td>F31.74</td>
<td>Bipolar disorder, in full remission, most recent episode manic</td>
</tr>
<tr>
<td>F31.75</td>
<td>Bipolar disorder, in partial remission, most recent episode depressed</td>
</tr>
<tr>
<td>F31.76</td>
<td>Bipolar disorder, in full remission, most recent episode depressed</td>
</tr>
<tr>
<td>F31.77</td>
<td>Bipolar disorder, in partial remission, most recent episode mixed</td>
</tr>
<tr>
<td>F31.78</td>
<td>Bipolar disorder, in full remission, most recent episode mixed</td>
</tr>
<tr>
<td>F31.81</td>
<td>Bipolar II disorder</td>
</tr>
<tr>
<td>F31.89</td>
<td>Other bipolar disorder</td>
</tr>
<tr>
<td>F31.9</td>
<td>Bipolar disorder, unspecified</td>
</tr>
<tr>
<td>G40.001</td>
<td>Localization-related (focal) (partial) idiopathic epilepsy and epileptic syndromes with seizures of localized onset, not intractable, with status epilepticus</td>
</tr>
<tr>
<td>G40.009</td>
<td>Localization-related (focal) (partial) idiopathic epilepsy and epileptic syndromes with seizures of localized onset, not intractable, without status epilepticus</td>
</tr>
<tr>
<td>G40.011</td>
<td>Localization-related (focal) (partial) idiopathic epilepsy and epileptic syndromes with seizures of localized onset, intractable, with status epilepticus</td>
</tr>
<tr>
<td>G40.019</td>
<td>Localization-related (focal) (partial) idiopathic epilepsy and epileptic syndromes with seizures of localized onset, intractable, without status epilepticus</td>
</tr>
<tr>
<td>G40.101</td>
<td>Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with simple partial seizures, not intractable, with status epilepticus</td>
</tr>
<tr>
<td>G40.109</td>
<td>Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with simple partial seizures, not intractable, without status epilepticus</td>
</tr>
<tr>
<td>G40.111</td>
<td>Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with simple partial seizures, intractable, with status epilepticus</td>
</tr>
<tr>
<td>G40.119</td>
<td>Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with simple partial seizures, intractable, without status epilepticus</td>
</tr>
<tr>
<td>G40.201</td>
<td>Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with complex partial seizures, not intractable, with status epilepticus</td>
</tr>
<tr>
<td>G40.209</td>
<td>Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with complex partial seizures, not intractable, without status epilepticus</td>
</tr>
<tr>
<td>G40.211</td>
<td>Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with complex partial seizures, intractable, with status epilepticus</td>
</tr>
<tr>
<td>G40.219</td>
<td>Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with complex partial seizures, intractable, without status epilepticus</td>
</tr>
<tr>
<td>G40.301</td>
<td>Generalized idiopathic epilepsy and epileptic syndromes, not intractable, with status epilepticus</td>
</tr>
<tr>
<td>G40.309</td>
<td>Generalized idiopathic epilepsy and epileptic syndromes, not intractable, without status epilepticus</td>
</tr>
<tr>
<td>G40.311</td>
<td>Generalized idiopathic epilepsy and epileptic syndromes, intractable, with status epilepticus</td>
</tr>
<tr>
<td>G40.319</td>
<td>Generalized idiopathic epilepsy and epileptic syndromes, intractable, without status epilepticus</td>
</tr>
<tr>
<td>G40.401</td>
<td>Other generalized epilepsy and epileptic syndromes, not intractable, with status epilepticus</td>
</tr>
<tr>
<td>G40.409</td>
<td>Other generalized epilepsy and epileptic syndromes, not intractable, without status epilepticus</td>
</tr>
</tbody>
</table>
ICD-10 Codes | Description
--- | ---
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
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 N/A
ICD-10 Additional Information

**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 or other Medicare auditor upon request.

This final LCD, effective 04/01/2016, combines JFA DL36147 into the JFB LCD so that both JFA and JFB contract numbers will have the same final MCD LCD number.
Sources of Information and Basis for Decision

References


Revision History Information

N/A

Associated Documents

Attachments N/A


Related National Coverage Documents N/A

Public Version(s) Updated on 01/29/2016 with effective dates 04/01/2016 - N/A

Keywords

- HLA-B
- MolDX
- Genetic
- genotype
- allele
- bipolar
- neuralgia
- epilepsy
- 81381

Read the LCD Disclaimer

Printed on 4/21/2016. Page 6 of 6