



PARAMOUNT

HMO & PPO  
MARKETPLACE  
MEDICARE – ELITE,  
MAP

## HLA-B\*1502 & HLA-B\*5701 Pharmacogenetic Testing

Policy Number: PG0437  
Last Review: 07/26/20018

### GUIDELINES

- This policy does not certify benefits or authorization of benefits, which is designated by each individual policyholder terms, conditions, exclusions and limitations contract. It does not constitute a contract or guarantee regarding coverage or reimbursement/payment. Self-Insured group specific policy will supersede this general policy when group supplementary plan document or individual plan decision directs otherwise.
- Paramount applies coding edits to all medical claims through coding logic software to evaluate the accuracy and adherence to accepted national standards.
- This medical policy is solely for guiding medical necessity and explaining correct procedure reporting used to assist in making coverage decisions and administering benefits.

### SCOPE

- Professional
- Facility

### DESCRIPTION

Pharmacogenomics testing is laboratory testing which has the potential to determine how an individual's genetic factors may affect the safety and effectiveness of that individual's response to a specific medication. The goal of pharmacogenomics testing is to reduce the incidence of adverse medication reactions while improving an individual's positive response to the medication. Additionally, some tests may help provide information on how well a specific treatment may work for an individual. Human leukocyte antigen-B (HLA-B) gene variations are associated with adverse reactions to some medications.

HLA-B\*1502 testing may be used in individuals of Asian ancestry to identify an increased risk of developing severe skin disorders (e.g., Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis) before taking carbamazepine (brand names Carbatrol, Equetro and Tegretol). Additionally, individuals who have tested positive for HLA-B\*1502 may be directed to a medication other than phenytoin.

HLA-B\*5701 screening is indicated prior to initiation of an abacavir-containing regimen to reduce the risk of a hypersensitivity reaction in HIV individuals. Abacavir (Ziagen) is a nucleoside analogue reverse transcriptase inhibitor indicated for use in combination with other antiretroviral drugs for the treatment of HIV-1 infection. Hypersensitivity in patients receiving abacavir indicated that respiratory symptoms (including cough, dyspnea, and pharyngitis) have occurred in approximately 20% of patients who have had hypersensitivity reactions. The frequency of the HLA-B\*5701 allele varies in different populations, occurring in whites 5 to 8%, Hispanics 4 to 7%, Asians less than 1%, Spaniards 1 to 4%, and rarely in Sub-Saharan Africans. A delay in diagnosis of hypersensitivity can result in abacavir being continued or re-introduced, leading to more severe hypersensitivity reactions, including life-threatening hypotension and death.

### POLICY

**Paramount Commercial Insurance Plans, Medicare Advantage Plans, and Paramount Advantage Medicaid**

**HLA-B\*1502 and HLA-B\*5701 genotyping (81381) requires prior authorization for all product lines.**

### COVERAGE CRITERIA

**Paramount Commercial Insurance Plans, Medicare Advantage Plans, and Paramount Advantage Medicaid**

HLA-B\*1502 genotyping is considered medically necessary when the following criteria are met:

- Patient is of Asian and Oceanian ancestry; AND
- Initial treatment with carbamazepine (Tegretol) or phenytoin (Dilantin) is planned

HLA-B\*5701 screening is considered medically necessary for persons infected with HIV-1 before commencing treatment with abacavir (Ziagen).

It is not expected that more than one test would be required in a given member's lifetime.

The following will be considered non-covered as applicable due to statutory exclusion, or lack of benefit, or not reasonable and necessary, or not separately billable (a component of the service per NCCI regulations):

- Tests considered screening in the absence of clinical signs and symptoms of disease
- Tests that do not provide the clinician with actionable data (information that will improve patient outcomes and/or change physician care and treatment of the patient)
- Tests that confirm a known diagnosis or known information (and no new data for decision making)
- Tests to determine risk for developing a disease or condition
- Tests without diagnosis specific indications
- Tests performed to measure the quality of a process
- Tests for Quality Control/Quality Assurance (QC/QA), i.e., tests performed to ensure a tissue specimen matches the patient
- Tests assessing the risk of allopurinol hypersensitivity reactions (HLA-B\*5801)

### CODING/BILLING INFORMATION

The inclusion or exclusion of a code in this section does not necessarily indicate coverage. Codes referenced in this clinical policy are for informational purposes only.

Codes that are covered may have selection criteria that must be met.

Payment for supplies may be included in payment for other services rendered.

<b>CPT CODE</b>	
<b>81381</b>	HLA Class I typing, high resolution (i.e., alleles or allele groups); one allele or allele group (e.g., B*57:01P), each
<b>ICD-10-CM CODES REQUIRED FOR COVERAGE OF CODE 81381</b>	
<b>B02.22</b>	Postherpetic trigeminal neuralgia
<b>B20</b>	Human immunodeficiency virus [HIV] disease
<b>F31.0</b>	Bipolar disorder, current episode hypomanic
<b>F31.10</b>	Bipolar disorder, current episode manic without psychotic features, unspecified
<b>F31.11</b>	Bipolar disorder, current episode manic without psychotic features, mild
<b>F31.12</b>	Bipolar disorder, current episode manic without psychotic features, moderate
<b>F31.13</b>	Bipolar disorder, current episode manic without psychotic features, severe
<b>F31.2</b>	Bipolar disorder, current episode manic severe with psychotic features
<b>F31.30</b>	Bipolar disorder, current episode depressed, mild or moderate severity, unspecified
<b>F31.31</b>	Bipolar disorder, current episode depressed, mild
<b>F31.32</b>	Bipolar disorder, current episode depressed, moderate
<b>F31.4</b>	Bipolar disorder, current episode depressed, severe, without psychotic features
<b>F31.5</b>	Bipolar disorder, current episode depressed, severe, with psychotic features
<b>F31.60</b>	Bipolar disorder, current episode mixed, unspecified
<b>F31.61</b>	Bipolar disorder, current episode mixed, mild
<b>F31.62</b>	Bipolar disorder, current episode mixed, moderate
<b>F31.63</b>	Bipolar disorder, current episode mixed, severe, without psychotic features
<b>F31.64</b>	Bipolar disorder, current episode mixed, severe, with psychotic features
<b>F31.70</b>	Bipolar disorder, currently in remission, most recent episode unspecified
<b>F31.71</b>	Bipolar disorder, in partial remission, most recent episode hypomanic
<b>F31.72</b>	Bipolar disorder, in full remission, most recent episode hypomanic
<b>F31.73</b>	Bipolar disorder, in partial remission, most recent episode manic
<b>F31.74</b>	Bipolar disorder, in full remission, most recent episode manic

<b>F31.75</b>	Bipolar disorder, in partial remission, most recent episode depressed
<b>F31.76</b>	Bipolar disorder, in full remission, most recent episode depressed
<b>F31.77</b>	Bipolar disorder, in partial remission, most recent episode mixed
<b>F31.78</b>	Bipolar disorder, in full remission, most recent episode mixed
<b>F31.81</b>	Bipolar II disorder
<b>F31.89</b>	Other bipolar disorder
<b>F31.9</b>	Bipolar disorder, unspecified
<b>G40.001</b>	Localization-related (focal) (partial) idiopathic epilepsy and epileptic syndromes with seizures of localized onset, not intractable, with status epilepticus
<b>G40.009</b>	Localization-related (focal) (partial) idiopathic epilepsy and epileptic syndromes with seizures of localized onset, not intractable, without status epilepticus
<b>G40.011</b>	Localization-related (focal) (partial) idiopathic epilepsy and epileptic syndromes with seizures of localized onset, intractable, with status epilepticus
<b>G40.019</b>	Localization-related (focal) (partial) idiopathic epilepsy and epileptic syndromes with seizures of localized onset, intractable, without status epilepticus
<b>G40.101</b>	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with simple partial seizures, not intractable, with status epilepticus
<b>G40.109</b>	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with simple partial seizures, not intractable, without status epilepticus
<b>G40.111</b>	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with simple partial seizures, intractable, with status epilepticus
<b>G40.119</b>	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with simple partial seizures, intractable, without status epilepticus
<b>G40.201</b>	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with complex partial seizures, not intractable, with status epilepticus
<b>G40.209</b>	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with complex partial seizures, not intractable, without status epilepticus
<b>G40.211</b>	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with complex partial seizures, intractable, with status epilepticus
<b>G40.219</b>	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with complex partial seizures, intractable, without status epilepticus
<b>G40.301</b>	Generalized idiopathic epilepsy and epileptic syndromes, not intractable, with status epilepticus
<b>G40.309</b>	Generalized idiopathic epilepsy and epileptic syndromes, not intractable, without status epilepticus
<b>G40.311</b>	Generalized idiopathic epilepsy and epileptic syndromes, intractable, with status epilepticus
<b>G40.319</b>	Generalized idiopathic epilepsy and epileptic syndromes, intractable, without status epilepticus
<b>G40.401</b>	Other generalized epilepsy and epileptic syndromes, not intractable, with status epilepticus
<b>G40.409</b>	Other generalized epilepsy and epileptic syndromes, not intractable, without status epilepticus
<b>G40.411</b>	Other generalized epilepsy and epileptic syndromes, intractable, with status epilepticus
<b>G40.419</b>	Other generalized epilepsy and epileptic syndromes, intractable, without status epilepticus
<b>G40.501</b>	Epileptic seizures related to external causes, not intractable, with status epilepticus
<b>G40.509</b>	Epileptic seizures related to external causes, not intractable, without status epilepticus
<b>G40.801</b>	Other epilepsy, not intractable, with status epilepticus
<b>G40.802</b>	Other epilepsy, not intractable, without status epilepticus
<b>G40.803</b>	Other epilepsy, intractable, with status epilepticus
<b>G40.804</b>	Other epilepsy, intractable, without status epilepticus
<b>G40.811</b>	Lennox-Gastaut syndrome, not intractable, with status epilepticus
<b>G40.812</b>	Lennox-Gastaut syndrome, not intractable, without status epilepticus
<b>G40.813</b>	Lennox-Gastaut syndrome, intractable, with status epilepticus
<b>G40.814</b>	Lennox-Gastaut syndrome, intractable, without status epilepticus
<b>G40.821</b>	Epileptic spasms, not intractable, with status epilepticus
<b>G40.822</b>	Epileptic spasms, not intractable, without status epilepticus
<b>G40.823</b>	Epileptic spasms, intractable, with status epilepticus
<b>G40.824</b>	Epileptic spasms, intractable, without status epilepticus
<b>G40.89</b>	Other seizures

<b>G40.901</b>	Epilepsy, unspecified, not intractable, with status epilepticus
<b>G40.909</b>	Epilepsy, unspecified, not intractable, without status epilepticus
<b>G40.911</b>	Epilepsy, unspecified, intractable, with status epilepticus
<b>G40.919</b>	Epilepsy, unspecified, intractable, without status epilepticus
<b>G50.0</b>	Trigeminal neuralgia
<b>G52.1</b>	Disorders of glossopharyngeal nerve
<b>Z17.0</b>	Estrogen receptor positive status [ER+]
<b>Z21</b>	Asymptomatic human immunodeficiency virus [HIV] infection status
<b>Z94.0</b>	Kidney transplant status
<b>Z94.1</b>	Heart transplant status
<b>Z94.2</b>	Lung transplant status
<b>Z94.3</b>	Heart and lungs transplant status
<b>Z94.81</b>	Bone marrow transplant status
<b>Z94.82</b>	Intestine transplant status
<b>Z94.83</b>	Pancreas transplant status
<b>Z94.84</b>	Stem cells transplant status

### REVISION HISTORY EXPLANATION

**ORIGINAL EFFECTIVE DATE: 07/26/2018**

Date	Explanation & Changes
<b>07/26/2018</b>	<ul style="list-style-type: none"> <li>Code 81381 now requires prior authorization for all product lines</li> <li>Policy created to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG)</li> </ul>
<b>12/28/2020</b>	<ul style="list-style-type: none"> <li>Medical policy placed on the new Paramount Medical policy format</li> </ul>
<b>03/03/2023</b>	<ul style="list-style-type: none"> <li>Medical Policy updated to reflect Medicaid coverage to Anthem as of 02/01/2023</li> </ul>

**Paramount reserves the right to review and revise our policies periodically when necessary. When there is an update, we will publish the most current policy to <https://www.paramounthealthcare.com/services/providers/medical-policies/> .**

### REFERENCES/RESOURCES

Centers for Medicare and Medicaid Services, CMS Manual System and other CMS publications and services

Ohio Department of Medicaid

American Medical Association, *Current Procedural Terminology (CPT®)* and associated publications and services

Centers for Medicare and Medicaid Services, Healthcare Common Procedure Coding System, HCPCS Release and Code Sets

U.S. Preventive Services Task Force, <http://www.uspreventiveservicestaskforce.org/>  
Industry Standard Review

Hayes, Inc.

Industry Standard Review