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

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

PARAMOUNT

ADVANTAGE | ELITE | HMO
INDIVIDUAL MARKETPLACE |
PROMEDICA MEDICARE
PLAN | PPO

GUIDELINES
This policy does not certify benefits or authorization of benefits, which is designated by each individual policyholder contract. Paramount applies coding edits to all medical claims through coding logic software to evaluate the accuracy and adherence to accepted national standards. This guideline is solely for explaining correct procedure reporting and does not imply coverage and reimbursement.

SCOPE
X Professional
X 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 (eg, 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
HLA-B*1502 and HLA-B*5701 genotyping (81381) requires prior authorization for all product lines.

COVERAGE CRITERIA
HMO, PPO, Individual Marketplace, Elite/ProMedica Medicare Plan, Advantage
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 appearance of a code in this section does not necessarily indicate coverage. Codes that are covered may have selection criteria that must be met. Payment for supplies may be included in payment for other services rendered.

CPT CODE	
81381	HLA Class I typing, high resolution (i.e., alleles or allele groups); one allele or allele group (e.g., B*57:01P), each
ICD-10-CM CODES REQUIRED FOR COVERAGE OF CODE 81381	
B02.22	Postherpetic trigeminal neuralgia
B20	Human immunodeficiency virus [HIV] disease
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
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
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+]
Z21	Asymptomatic human immunodeficiency virus [HIV] infection status
Z94.0	Kidney transplant status
Z94.1	Heart transplant status
Z94.2	Lung transplant status
Z94.3	Heart and lungs transplant status
Z94.81	Bone marrow transplant status
Z94.82	Intestine transplant status
Z94.83	Pancreas transplant status
Z94.84	Stem cells transplant status

REVISION HISTORY EXPLANATION
ORIGINAL EFFECTIVE DATE: 07/26/2018
07/26/18: Code 81381 now requires prior authorization for all product lines. Policy created to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG).
12/28/2020: Medical policy placed on the new Paramount Medical policy format

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
Industry Standard Review
Hayes, Inc.