Pharmacogenomics Testing

Humana
Medicaid Medical Coverage Policy

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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.

Behavioral health pharmacogenomic testing are laboratory tests that analyze an individual's genetic profile to help predict response to medications commonly prescribed for mental health conditions. Examples include, but are not limited to, **GeneSight Psychotropic Test, IDgenetix, MindX One Blood Test – Anxiety, Psych HealthPGx Panel, Serotonin Receptor Genotype and Tempus nP**.

ChemoFx assay is a lab test that evaluates how an individual's solid tumor may respond, either sensitively or resistantly, to different chemotherapy drugs.

Comprehensive pharmacogenomic testing analyzes an individual's genetic makeup to determine response to many medications for a variety of conditions such as psychiatric diagnoses, oncologic indications, acute and chronic pain, cardiovascular and neurological diseases. Examples include, but are not limited to, **EffectiveRX Comprehensive Panel and RightMed Comprehensive Test.**

***DPYD* and *TYMS* genotype testing** detects genetic variations in the *DPYD* and *TYMS* gene, respectively, to identify individuals at risk of severe toxicity from fluoropyrimidine chemotherapy (eg, capecitabine and fluorouracil).

EpiSwitch CiRT (Checkpoint inhibitor Response Test) is a blood-based test that evaluates the likelihood of an individual's cancer to respond to immune checkpoint inhibitor therapy.

***IFNL3* genotype testing** examines the *IFNL3* gene to purportedly predict treatment outcomes for hepatitis C virus (HCV) infection.

Mind.Px is a next-generation sequencing (NGS) test that analyzes capture RNA from psoriasis lesions using a dermal biomarker patch. The test has been proposed to predict to determine biologic drug response to certain therapies for individuals with psoriasis.

***NUDT15* and *TPMT* genotype testing** analyzes the *NUDT15* and *TPMT* genes to determine if an individual is at risk of an adverse event or is a poor responder to thiopurine drugs (eg, azathioprine, mercaptopurine, thioguanine).

***SLCO1B1* genotype testing** analyzes variations in the *SLCO1B1* gene to help predict an individual's response to statin medications and has been suggested to reduce the risk of statin-related muscle side effects such as myopathy.

VitaRisk is a genetic test to purportedly assess an individual's of developing advanced age-related macular degeneration (AMD). The test has been proposed to aid in determining the most appropriate vitamin supplements to prevent loss of vision.

Coverage Determination

***DPYD* Genotype Testing**

Humana members may be eligible under the Plan for ***DPYD* genotype testing (81232)** for either of the following indications:

- Guide medication dosing when performed prior to the initiation of fluoropyrimidine medication therapy (eg, capecitabine, fluorouracil)[9,49,64]; **OR**
- Severe or unexpected toxicity from fluoropyrimidine medication therapy (eg, capecitabine, fluorouracil)[49]

***NUDT15* and *TPMT* Genotype Testing**

Humana members may be eligible under the Plan for ***NUDT15* (81306) and/or *TPMT* (84433) genotype testing** for either of the following indications:

- Guide medication dosing when performed prior to the initiation of thiopurine medication therapy (eg, azathioprine, mercaptopurine, thioguanine)[1,13,39,41,64]; **OR**

- Severe toxicity from thiopurine medication therapy (eg, azathioprine, mercaptopurine, thioguanine)[41]

Coverage Limitations

Humana members may **NOT** be eligible under the Plan for the following pharmacogenomics testing:

- Cytochrome P450 1A2 Genotype (0031U)
- EffectiveRX Comprehensive Panel (0438U)
- Genomind Pharmacogenetics Report – Full (0423U)
- *IFNL3* genotype testing (81283)
- MindX One Blood Test – Anxiety (0437U)
- Psych HealthPGx Panel (0173U)
- RightMed Comprehensive Test (0349U)
- RightMed Comprehensive Test Excludes F2 and F5 (0348U)
- RightMed Gene Report (0350U)
- RightMed Gene Test Excludes F2 and F5 (0434U)
- RightMed Oncology Gene Report (0460U)
- RightMed Oncology Medication Report (0461U)
- Serotonin Receptor Genotype (0033U)
- Tempus nP (0419U)

A review of the current medical literature shows that there is **no evidence** to determine that these services are standard medical treatments. There is an absence of current, widely-used treatment guidelines or acceptable clinical literature examining benefit and long-term clinical outcomes establishing the value of these services in clinical management.

Humana members may **NOT** be eligible under the Plan for the following pharmacogenomics testing:

- ChemoFx Assay (81535/81536)[6,29,40,50]
- CNT (CEP72, NUDT15 and TPMT) Genotyping Panel (0286U)[31]
- EpiSwitch CiRT (0332U)[32]
- GeneSight Psychotropic test (0345U)
- Genomind Professional PGx Express CORE (0175U)[16,23,36,51,61,62]
- IDgenetix (0411U)
- Mayo Clinic Catechol-O-Methyltransferase (COMT) Genotype (0032U)[11]
- Mind.Px (0258U)[18,33,57]
- *SLCO1B1* genotype testing (81328)[26,42]
- *TYMS* genotype testing (81346)[9,49]
- VitaRisk (0205U)[1,45]

A review of the current medical literature shows that the **evidence is insufficient** to determine that these services are standard medical treatments. There is an absence of current, widely-used treatment guidelines or acceptable clinical literature examining benefit and long-term clinical outcomes establishing the value of these services in clinical management.

Coding Information

Any codes listed on this policy are for informational purposes only. Do not rely on the accuracy and inclusion of specific codes. Inclusion of a code does not guarantee coverage and/or reimbursement for a service or procedure.

CPT® Code(s)	Description	Comments
81232	DPYD (dihydropyrimidine dehydrogenase) (eg, 5-fluorouracil/5-FU and capecitabine drug metabolism), gene analysis, common variant(s) (eg, *2A, *4, *5, *6)	
81283	IFNL3 (interferon, lambda 3) (eg, drug response), gene analysis, rs12979860 variant	
81306	NUDT15 (nudix hydrolase 15) (eg, drug metabolism) gene analysis, common variant(s) (eg, *2, *3, *4, *5, *6)	
81328	SLCO1B1 (solute carrier organic anion transporter family, member 1B1) (eg, adverse drug reaction), gene analysis, common variant(s) (eg, *5)	
81346	TYMS (thymidylate synthetase) (eg, 5-fluorouracil/5-FU drug metabolism), gene analysis, common variant(s) (eg, tandem repeat variant)	
81535	Oncology (gynecologic), live tumor cell culture and chemotherapeutic response by DAPI stain and morphology, predictive algorithm reported as a drug response score; first single drug or drug combination	
81536	Oncology (gynecologic), live tumor cell culture and chemotherapeutic response by DAPI stain and morphology, predictive algorithm reported as a drug response score; each additional single drug or drug combination (List separately in addition to code for primary procedure)	
84433	Thiopurine S-methyltransferase (TPMT)	
0031U	CYP1A2 (cytochrome P450 family 1, subfamily A, member 2)(eg, drug metabolism) gene analysis, common variants (ie, *1F, *1K, *6, *7)	
0033U	HTR2A (5-hydroxytryptamine receptor 2A), HTR2C (5-hydroxytryptamine receptor 2C) (eg, citalopram metabolism) gene analysis, common variants (ie, HTR2A rs7997012 [c.614-2211T>C], HTR2C rs3813929 [c.-759C>T] and rs1414334 [c.551-3008C>G])	
0173U	Psychiatry (ie, depression, anxiety), genomic analysis panel, includes variant analysis of 14 genes	
0175U	Psychiatry (eg, depression, anxiety), genomic analysis panel, variant analysis of 15 genes	

0205U	Ophthalmology (age-related macular degeneration), analysis of 3 gene variants (2 CFH gene, 1 ARMS2 gene), using PCR and MALDI-TOF, buccal swab, reported as positive or negative for neovascular age-related macular-degeneration risk associated with zinc supplements	
0258U	Autoimmune (psoriasis), mRNA, next-generation sequencing, gene expression profiling of 50-100 genes, skin-surface collection using adhesive patch, algorithm reported as likelihood of response to psoriasis biologics	
0286U	CEP72 (centrosomal protein, 72-KDa), NUDT15 (nudix hydrolase 15) and TPMT (thiopurine S-methyltransferase) (eg, drug metabolism) gene analysis, common variants	
0332U	Oncology (pan-tumor), genetic profiling of 8 DNA-regulatory (epigenetic) markers by quantitative polymerase chain reaction (qPCR), whole blood, reported as a high or low probability of responding to immune checkpoint-inhibitor therapy	
0345U	Psychiatry (eg, depression, anxiety, attention deficit hyperactivity disorder [ADHD]), genomic analysis panel, variant analysis of 15 genes, including deletion/duplication analysis of CYP2D6	
0348U	Drug metabolism or processing (multiple conditions), whole blood or buccal specimen, DNA analysis, 25 gene report, with variant analysis and reported phenotypes	
0349U	Drug metabolism or processing (multiple conditions), whole blood or buccal specimen, DNA analysis, 27 gene report, with variant analysis, including reported phenotypes and impacted gene-drug interactions	
0350U	Drug metabolism or processing (multiple conditions), whole blood or buccal specimen, DNA analysis, 27 gene report, with variant analysis and reported phenotypes	
0411U	Psychiatry (eg, depression, anxiety, attention deficit hyperactivity disorder [ADHD]), genomic analysis panel, variant analysis of 15 genes, including deletion/duplication analysis of CYP2D6	
0419U	Neuropsychiatry (eg, depression, anxiety), genomic sequence analysis panel, variant analysis of 13 genes, saliva or buccal swab, report of each gene phenotype	
0423U	Psychiatry (eg, depression, anxiety), genomic analysis panel, including variant analysis of 26 genes, buccal swab, report including metabolizer status and risk of drug toxicity by condition	

0434U	Drug metabolism (adverse drug reactions and drug response), genomic analysis panel, variant analysis of 25 genes with reported phenotypes	
0437U	Psychiatry (anxiety disorders), mRNA, gene expression profiling by RNA sequencing of 15 biomarkers, whole blood, algorithm reported as predictive risk score	
0438U	Drug metabolism (adverse drug reactions and drug response), buccal specimen, gene-drug interactions, variant analysis of 33 genes, including deletion/duplication analysis of CYP2D6, including reported phenotypes and impacted gene-drug interactions	
0460U	Oncology, whole blood or buccal, DNA single-nucleotide polymorphism (SNP) genotyping by real-time PCR of 24 genes, with variant analysis and reported phenotypes	
0461U	Oncology, pharmacogenomic analysis of single-nucleotide polymorphism (SNP) genotyping by real-time PCR of 24 genes, whole blood or buccal swab, with variant analysis, including impacted gene-drug interactions and reported phenotypes	
CPT® Category III Code(s)	**Description**	**Comments**
No code(s) identified		
HCPCS Code(s)	**Description**	**Comments**
No code(s) identified		

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Change Summary

04/01/2025 New Policy.
05/06/2025 Update, Coverage Change. Provider Claims Codes Update.