# Genetic testing: pharmacogenetics

These services may or may not be covered by your HealthPartners plan. Please see your plan documents for your specific coverage information. If there is a difference between this general information and your plan documents, your plan documents will be used to determine your coverage.

## Administrative Process

Prior authorization is not required for the following:

- UGT1A1 genotyping (CPT 81350)
- CYP3A5 (81231)
- TPMT and NUDT15 Variant Analysis
- VKORC1 Variant Analysis

Prior authorization is not applicable for the following tests as they are considered investigational/experimental:

- COMT genotyping (CPT 0032U)
- CYP1A2 genotyping (CPT 0031U)
- Pharmacogenetic Panel Tests
- TYMS genotyping

Prior authorization is required for all other pharmacogenetic testing including:

- Other Single Gene Variant Analysis not listed above
- BCHE Variant Analysis
- HLA variant analysis
- CYP2C19 (CPT 81225, 81479)
- CYP4F2
- DPYD Variant Analysis (CPT 81232)
- KIF6
- OPRM1
- CYP2C9 Variant Analysis
- CYP2D6 Variant Analysis (CPT 81226, 0070U-0076U)
- Testing that is associated with a procedure code listed in “Box A”, below.

Tests that require prior authorization will be reviewed for medical necessity of the testing as a whole. That is, a single coverage decision will apply to all of the tests, services, and/or procedure codes associated with the genetic test, whether they are requested/billed together or separately.

| **Box A: Genetic testing procedure codes that require prior authorization** |
|---|
| Molecular pathology procedures, Tier 2 or unlisted (CPT 81400-81408, 81479) |
| Unlisted multianalyte assays (CPT 81599) |
| Any other listed or unlisted laboratory/pathology CPT code when it is used in association with a genetic test |

## Policy Reference Table

*If available, codes are listed below for informational purposes only, and do not guarantee member coverage or provider reimbursement. The list may not be all-inclusive.*

| Coverage Criteria Sections | Example Tests (Labs) | Common CPT Codes | Common ICD Codes |
|---|---|---|---|
| Pharmacogenetic Panel Tests | GeneSight Psychotropic (Myriad Genetics) | 0345U | B20, C00.0-C96.9, D00.0-D49.9, E75.22, F01-F99, G10, G71.14, G89.0-G89.4, I20.0, I21.01-I22.9, I24.1, I25.110, I26.01-I26.99, I48.0, I60.00-I66.99, I73, I82.210-I82.91, K50.00-K50.019 K51.00-K51.319, R52, R79.9, |
| | Professional PGX (formerly Genecept Assay) (Genomind) | 81418 | |
| | PGxOne (Admera Health) | | |
| | Genomind Professional PGX Express CORE | 0175U | |
| | Cytochrome P450 Genotyping Panel (ARUP Laboratories) | 81418 | |
| | OneOme RightMed Pharmacogenomic Test (OneOme) | 0347U | |

| | | | |
|---|---|---|---|
| | RightMed Comprehensive Test Exclude F2 and F5 (OneOme, LLC) | 0348U | T46.6X1A-T46.6X6S, Z13.71-Z13.79, Z80.3, Z81.8, Z82.49, Z85.3, Z86.000, Z86.59, Z86.71-Z86.79 |
| | RightMed Comprehensive Test (OneOme, LLC) | 0349U | |
| | RightMed Gene Report (OneOme, LLC) | 0350U | |
| | RightMed Oncology Gene Report (OneOme, LLC) | 0460U | |
| | RightMed Oncology Medication Report (OneOme, LLC) | 0461U | |
| | Focused Pharmacogenomics Panel (Mayo Medical Laboratories) | 0029U | |
| | Psych HealthPGx Panel (RPRD Diagnostics) | 0173U | |
| | CNT Genotyping Panel (RPRD Diagnostics) | 0286U | |
| | PersonalisedRX (Lab Genomics LLC) | 0380U | |
| | Serotonin Receptor Genotype (HTR2A and HTR2C), (Mayo Medical Laboratories) | 0033U | |
| | Effective RX Comprehensive Panel (GENETWORx) | 0438U | |
| | RightMed Gene Test Exclude F2 and F5 (OneOme LLC) | 0434U | |
| | Genomind Pharmacogenetics Report (Genomind, Inc) | 0423U | |
| | Tempus nP (Tempus) | 0419U | |
| | IDgenetix (Castle Biosciences) | 0411U | |
| | Medication Management Neuropsychiatric Panel (RCA Laboratory) | 0392U | |
| | RightMed Mental Health Gene Report (OneOme, LLC) | 0476U | |
| | RightMed Mental Health Medication Report (OneOme, LLC) | 0477U | |
| | MyGenVar Pharmacogenomics Test (Geisinger Medical Laboratories) | 0516U | |
| **Pharmacogenetic Single Gene Tests** | | | |
| *BCHE* Variant Analysis | BCHE Single Gene Test (Blueprint Genetics) | 81479 | Z01.81, Z01.810, Z01.811, Z01.818, Z01.89 |
| *CYP2C9* Variant Analysis | Cytochrome P450 2C9 Genotype, (Quest Diagnostics) | 81227 | E78.00, E78.1, G35, I21.0-I22.9, I26.01-I26.99, I48.0, I60.00-I66.99, I82.210-I82.91, Z86.71-Z86.79 |
| *CYP2C19* Variant Analysis | CYP2C19 Single Gene Test (Blueprint Genetics) | 81225, 81479 | C64, F32, I21.0-I22.9, I26.01-I26.99, I48.0, I60.00-I66.99, I82.210-I82.91, K21.9, L20, Q85.83, |

HealthPartners

| | | | |
|---|---|---|---|
| | | | R56.9, R68.82, Z86.71-Z86.79 |
| *CYP2D6* Variant Analysis | CYP2D6 (ARUP Laboratories) | 81226 | C50.011-C50.929, C79.81, D05.00-D05.92, D07.30-D07.39, E11.9, E75.22, F11, F20.9, F31, F33, F84.0, F90, F95.2, G10, G24, G47.419, I10, I20.0, I21.01-I22.9, I24.1, I25.110, I48, I63.50-I63.549, I66.01-I66.9, I73, K21.9, R42, R52, T75.3, Z13.71-Z13.79, Z80.3, Z85.3, Z86.000 |
| | CYP2D6 Common Variants and Copy Number (Mayo Clinic Laboratories) | 0070U | |
| | CYP2D6 Full Gene Sequencing (Mayo Clinic Laboratories) | 0071U | |
| | CYP2D6-2D7 Hybrid Gene Targeted Sequence Analysis (Mayo Clinic Laboratories) | 0072U | |
| | CYP2D7-2D6 Hybrid Gene Targeted Sequence Analysis (Mayo Clinic Laboratories) | 0073U | |
| | CYP2D6 Nonduplicated Gene Analysis (Mayo Clinic Laboratories) | 0074U | |
| | CYP2D6 5' gene duplication/multiplication targeted sequence analysis (Mayo Clinic Laboratories) | 0075U | |
| | CYP2D6 3' gene duplication/multiplication targeted sequence analysis (Mayo Clinic Laboratories) | 0076U | |
| *CYP3A5* Variant Analysis | Pain Management, CYP450 3A5 Genotype, Qualitative (Quest Diagnostics) | 81231 | T86, Z79.6, Z94 |
| *CYP4F2* Variant Analysis | CYP4F2 Single Gene Test (Blueprint Genetics) | 81479 | I21.0-I22.9, I26.01-I26.99, I48.0, I60.00-I66.99, I82.210-I82.91, Z86.71-Z86.79 |
| *DPYD* Variant Analysis | DPYD Genotyping (Labcorp) | 81232 | C00.0-C96.9, D00.0-D49.9 |
| HLA-A*02:01 Variant Analysis | HLA A 02:01 Determination (Quest Diagnostics) | 81379, 81380, 81381 | C69, C69.4 |
| | HLA-A*02:01-Specific (LabCorp) | | |
| | HLA-A*02:01 Determination (Versiti) | | |
| *HLA-B*15:02 Variant Analysis | HLA-B*15:02 Carbamazepine Sensitivity (Labcorp) | 81381 | G40 |
| *HLA-B*57:01 Variant Analysis | HLA B*57:01 Abacavir Hypersensitivity (Labcorp) | 81381 | B20, Z21 |
| *NAT2* Variant Analysis | NAT2 single gene test (Blueprint Genetics) | 81479 | G73, M35.9 |
| *TPMT* and NUDT15 Variant Analysis | Thiopurine S-Methyltransferase (*TPMT*) Genotype (Quest Diagnostics) | 81335 | C91.0, K50.00-K50.90, K51.00-K51.319, M35.9, M05-M06.9, C85.90 |
| | *TPMT* and *NUDT15* (ARUP Laboratories) | 81335, 81306 | |
| | Thiopurine Methyltransferase (*TPMT*) and Nudix Hydrolase (*NUDT15*) Genotyping (Mayo Clinic Laboratories) | 0034U | |
| | NT (*NUDT15* and *TPMT*) genotyping panel (RPRD Diagnostics) | 0169U | |

| | | | |
|---|---|---|---|
| *UGT1A1* Variant Analysis | UGT1A1 Irinotecan Toxicity (Labcorp) | 81350 | B20, C18, C19, C20, C50, C84, E80.4 |
| *UGT2B17* Variant Analysis | UGT2B17 Single Gene (Fulgent Genetics) | 81479 | C25, C64, C71, C72, Q85.83 |
| *VKORC1* Variant Analysis | VKORC1 Single Gene Test (Blueprint Genetics) | 81355, 81479 | I21.0-I22.9, I26.01-I26.99, I48.0, I60.00-I66.99, I82.210-I82.91, Z86.71-Z86.79 |
| Warfarin Sensitivity Analysis Panels | Warfarin Response Genotype (Mayo Medical Laboratories) | 0030U | I21, I26, I48 |
| | Accutype Warfarin (Quest) | 81227, 81355 | |
| Other Single Gene Variant Analysis | Catechol-O-Methyltransferase (COMT) Genotype (Mayo Clinic Laboratories) | 0032U | F01-F69, F80-F99, G20, Z81.8, Z86.59 |
| | COMT single gene test (Blueprint Genetics) | 81479 | |
| | Cytochrome P450 1A2 Genotype (Mayo Clinic Laboratories) | 0031U | F01-F69, F80-F99, Z81.8, Z86.59 |
| | CYP1A2 single gene test (Blueprint Genetics) | 81479 | |
| | Cardio IQ KIF6 Genotype (Quest Diagnostics) | 81479 | E78.0-E78.9, R79.9, Z82.49 |
| | Opioid Receptor, mu OPRM1 Genotype, 1 Variant, (ARUP Laboratories) | 81479 | G89.0-G89.4 |
| | TYMS Single Gene (Sequencing & Deletion/Duplication) (Fulgent Genetics) | 81479 | C00.0-C96.9, D00.0-D49.9 |



## Coverage

### Pharmacogenetic Panel Tests

1. The use of pharmacogenetic testing panels is considered **investigational*** for all indications.

*See TPMT and NUDT15 Variant Analysis below for coverage criteria. This test involves analysis of more than one gene, but is not considered experimental/investigational as a panel ("panel" defined as a genetic test analyzing more than one gene)

Back to top

### Pharmacogenetic Single Gene Tests

***BCHE Variant Analysis***

1. BCHE variant analysis to determine drug metabolizer status is considered **medically necessary** when:
   - A. The member is being considered for or is currently undergoing treatment with either of the following:
     - i. Mivacurium (e.g., Mivacron*), **or**
     - ii. Succinylcholine* (e.g., Anectine, Suxamethonium)
2. BCHE variant analysis to determine drug metabolizer status is considered **investigational** for all other indications.

*Commonly used as a muscle relaxant during surgery or intubation

Back to top

***CYP2C9* Variant Analysis**

1. *CYP2C9* variant analysis to determine drug metabolizer status is considered **medically necessary** when:
   - A. The member is being considered for or is currently undergoing treatment with and of the following:
     - i. Siponimod[1] (Mayzent), **or**
     - ii. Celecoxib[2] (e.g., Celebrex, Elyxyb), **or**

iii. Dronabinol[3] (e.g., Marinol, Syndros), **or**
iv. Erdafitinib[4] (e.g., Balversa), **or**
v. Flurbiprofen[5] (e.g., Ansaid), **or**
vi. Fosphenytoin[6] (e.g., Cerebyx, Sesquient), **or**
vii. Meloxicam[7] (e.g., Anjeso, Mobic, Vivlodex, Qmiiz ODT), **or**
viii. Nateglinide[8] (e.g., Starlix), **or**
ix. Phenytoin[9] (e.g., Dilantin, Phenytek), **or**
x. Piroxicam[10] (e.g., Feldene), **or**
xi. Warfarin[11] (e.g., Coumadin, Jantoven)

2. *CYP2C9* variant analysis to determine drug metabolizer status is considered **investigational** for all other indications.

1 Commonly prescribed for individuals diagnosed with multiple sclerosis
2 Commonly prescribed for treating pain or inflammation
3 Commonly prescribed for treating loss of appetite and severe nausea and vomiting
4 Commonly prescribed for treatment of bladder cancer
5 Commonly prescribed for treatment of pain or inflammation
6 Commonly prescribed for preventing or controlling seizures
7 Commonly prescribed for treating pain, inflammation, or severe pain
8 Commonly prescribed for blood sugar control in individuals with type II diabetes
9 Commonly prescribed for treatment of seizures
10 Commonly prescribed to treat pain or inflammation
11 Commonly prescribed to reduce the formation of blood clots

Back to top

***CYP2C19* Variant Analysis**

1. *CYP2C19* variant analysis to determine drug metabolizer status is considered **medically necessary** when:
   A. The member is being considered for or is currently undergoing treatment with any of the following:
      i. Clopidogrel[1] (e.g., Plavix); **or**
      ii. Abrocitinib[2] (e.g., Cibinqo), **or**
      iii. Belzutifan[3] (e.g., Welireg), **or**
      iv. Brivaracetam[4] (e.g., Briviact, Brivajoy), **or**
      v. Citalopram[5] (e.g., Celexa), **or**
      vi. Clobazam[6] (e.g., Onfi), **or**
      vii. Flibanserin[7] (e.g., Addyi), **or**
      viii. Pantoprazole[8] (e.g., Protonix)
2. *CYP2C19* variant analysis to determine drug metabolizer status is considered **investigational** for all other indications.

1 Commonly prescribed after angina or cardiac arrest to lower risk of stroke and blood clots
2 Commonly prescribed for eczema
3 Commonly prescribed to treat tumors in individuals with Von Hippel-Lindau syndrome
4 Commonly prescribed to treat seizures
5 Commonly prescribed for treatment of depression and major depressive disorder
6 Commonly prescribed for treatment of seizures caused by Lennox-Gastaut syndrome
7 Commonly prescribed for low libido in pre-menopausal women
8 Commonly prescribed for treatment of erosive esophagitis caused by GERD, and Zollinger-Ellison syndrome

Back to top

***CYP2D6* Variant Analysis**

1. *CYP2D6* variant analysis to determine drug metabolizer status is considered **medically necessary** when:
   A. The member is being considered for or currently undergoing treatment with any of the following:
      i. Eliglustat[1] (e.g., Cerdelga), **or**
      ii. Tetrabenazine[2] (e.g., Xenazine®), **or**
      iii. Amphetamine[3] (e.g., Adzenys, Dyanavel, Evekeo) **or**
      iv. Aripiprazole[4] (e.g., Abilify, Abilify Maintena), **or**
      v. Aripiprazole lauroxil[5] (e.g., Aristada), **or**
      vi. Atomoxetine[6] (e.g., Strattera), **or**
      vii. Brexpiprazole[7] (e.g., Rexulti), **or**
      viii. Clozapine[8] (e.g., Versacloz, FazaClo, Clozaril), **or**
      ix. Deutetrabenazine[9] (e.g., Austedo), **or**
      x. Gefitinib[10] (e.g., Iressa), **or**
      xi. Iloperidone[11] (e.g., Fanapt), **or**
      xii. Lofexidine[12] (e.g., Lucemyra), **or**

xiii. Meclizine[13] (e.g., Antivert, Bonine, Dramamine, Verticalm, Zentrip), **or**
xiv. Metoclopramide[14] (e.g., Reglan, Metozolv), **or**
xv. Oliceridine[15] (e.g., Olinvyk), **or**
xvi. Pimozide[16] (e.g., Orap), **or**
xvii. Pitolisant[17] (e.g., Wakix), **or**
xviii. Propafenone[18] (e.g., Rythmol), **or**
xix. Thioridazine[19] (e.g., Mellaril), **or**
xx. Tramadol[20] (e.g., ConZip, Ultram), **or**
xxi. Valbenazine[21] (e.g., Ingrezza), **or**
xxii. Venlafaxine[22] (e.g., Effexor), **or**
xxiii. Vortioxetine[23] (e.g., Trintellix, Brintellix), **or**
xxiv. Codeine[24]

2. *CYP2D6* variant analysis to determine drug metabolizer status is considered **investigational** for all other indications, including:
   A. For the purpose of managing treatment with tamoxifen for women at high risk for or with breast cancer.

1 Commonly prescribed for treatment of Gaucher disease
2 Commonly prescribed for treatment of involuntary movements (chorea) caused by Huntington disease
3 Commonly prescribed for treatment of hyperactivity, impulse control, and attention deficit hyperactivity disorder (ADHD)
4 Commonly prescribed for schizophrenia, bipolar I disorder, and major depressive disorder
5 Commonly prescribed for schizophrenia
6 Commonly prescribed for treatment of attention deficit hyperactivity disorder (ADHD)
7 Commonly prescribed for treatment of schizophrenia and major depressive disorder
8 Commonly prescribed for treatment of schizophrenia
9 Commonly prescribed for treatment of involuntary muscle movements (chorea) caused by Huntington disease, and tardive dyskinesia
10 Commonly prescribed for treatment of non-small cell lung cancer
11 Commonly prescribed for treatment of schizophrenia
12 Commonly prescribed for treatment of opioid withdrawal symptoms
13 Commonly prescribed for treatment of motion sickness and vertigo
14 Commonly prescribed for treatment of heartburn caused by GERD, gastroparesis, nausea and vomiting, and to aid in certain medical procedures involving the stomach or intestines
15 Commonly prescribed for treatment of severe pain
16 Commonly prescribed for treatment of Tourette's syndrome
17 Commonly prescribed for treatment of excessive daytime sleepiness or sudden loss of muscle strength (cataplexy) related to narcolepsy
18 Commonly prescribed for treatment of heart rhythm disorders
19 Commonly prescribed for treatment of schizophrenia
20 Commonly prescribed for treatment of moderate to severe pain
21 Commonly prescribed for treatment of tardive dyskinesia
22 Commonly prescribed for treatment of major depressive disorder, anxiety, and panic disorder
23 Commonly prescribed for treatment of major depressive disorder
24 Commonly prescribed for treatment of mild to moderately severe pain, and to help reduce coughing

Back to top

***CYP3A5 Variant Analysis***

1. CYP3A5 variant analysis to determine drug metabolizer status is considered **medically necessary** when:
   A. The member is being considered for or is currently undergoing treatment with tacrolimus[1] (e.g., Protopic, Envarsus, Astagraf, Prograf).
2. CYP3A5 variant analysis to determine drug metabolizer status is considered **investigational** for all other indications.

1 Commonly prescribed to individuals who have undergone a heart, kidney, liver, or lung transplant

Back to top

***CYP4F2* Variant Analysis**

1. *CYP4F2* variant analysis to determine drug metabolizer status is considered medically necessary when:
   A. The member is being considered for or is currently undergoing treatment with warfarin[1] (e.g., Coumadin, Jantoven).
2. *CYP4F2* variant analysis to determine drug metabolizer status is considered **investigational** for all other indications.

1 Commonly prescribed to reduce the formation of blood clots

Back to top

***DPYD* Variant Analysis**

1. *DPYD* variant analysis to determine drug metabolizer status is considered **medically necessary** when:

A. The member being considered for or is currently undergoing treatment with either of the following:
   i. Fluorouracil[1] (e.g., Carac, Efudex, Tolak, Fluoroplex) **or**
   ii. Capecitabine[1] (e.g., Xeloda®).

2. *DPYD* variant analysis to determine drug metabolizer status is considered **investigational** for all other indications.

1 Commonly prescribed for individuals diagnosed with colorectal, breast, and aerodigestive tract tumors

Back to top

**HLA-A*02:01 Variant Analysis**

1. HLA-A*02:01 variant analysis is considered **medically necessary** when the member meets the following:
   A. The member is age 18 or older, **and**
   B. The member has a diagnosis of one of the following:
      i. Metastatic uveal melanoma, **or**
      ii. Unresectable uveal melanoma, **and**
   C. The member has not had progression of disease.
2. HLA-A*02:01 variant analysis is considered **investigational** for all other indications.

Back to top

**HLA-B*15:02 Variant Analysis**

1. *HLA-B*15:02* variant analysis to determine drug metabolizer status is considered **medically necessary** when:
   A. The member is being considered for or is currently undergoing treatment with any of the following:
      i. Carbamazepine containing therapy[1] (e.g., Tegretol, Carbatrol, Epitol, Equetro), **or**
      ii. Phenytoin[2] (e.g., Dilantin, Phenytek), **or**
      iii. Fosphenytoin[2] (e.g., Cerebyx, Sesquient).
2. *HLA-B*15:02* variant analysis to determine drug metabolizer status is considered **investigational** for all other indications.

1 Commonly prescribed for individuals with epilepsy, trigeminal neuralgia, or bipolar disorder
2 Commonly prescribed for treatment of seizures

Back to top

***HLA-B*57:01* Variant Analysis**

1. *HLA-B*57:01* variant analysis to determine drug metabolizer status is considered **medically necessary** when:
   A. The member is being considered for or is currently being treated with abacavir[1] (e.g., Ziagen).
2. *HLA-B*57:01* variant analysis to determine drug metabolizer status is considered **investigational** for all other indications.

[1] Commonly prescribed for individuals with HIV

Back to top

***NAT2* Variant Analysis**

1. NAT2 variant analysis to determine drug metabolizer status is considered medically necessary when:
   A. The member is being considered for or is currently undergoing treatment with amifampridine/amifampridine phosphate[1] (e.g., Firdapse, Ruzurgi)
2. NAT2 variant analysis to determine drug metabolizer status is considered **investigational** for all other indications.

1 Commonly prescribed for treatment of Lambert-Eaton myasthenic syndrome

Back to top

***TPMT* and *NUDT15* Variant Analysis**

1. *TMPT* and *NUDT15* variant analysis to determine drug metabolizer status is considered **medically necessary** when:
   A. The member is being considered for or is currently undergoing treatment with any of the following:
      i. Aazathioprine[1] (e.g., Imuran and Azasan), **or**
      ii. Mercaptopurine[2] (e.g., Purinethol, Purixan), **or**
      iii. Thioguanine[3] (e.g., Tabloid), **or**
   B. The member is on thiopurine therapy, **and**
      i. The member has had abnormal complete blood count results that do not respond to dose reduction.
2. *TPMT* and *NUDT15* variant analysis to determine drug metabolizer status is considered **investigational** for all other indications.

1 Commonly prescribed for treatment of avoiding rejection of a transplanted organ and rheumatoid arthritis
2 Commonly prescribed for treatment of acute lymphoblastic or lymphocytic leukemia
3 Commonly prescribed for treatment of acute nonlymphocytic leukemia

Back to top

***UGT1A1* Variant Analysis**

1. UGT1A1 variant analysis to determine drug metabolizer status is considered **medically necessary** when:
   - A. The member is being considered for or is currently undergoing treatment with any of the following:
     - i. Irinotecan[1](e.g., Onivyde, Camptosar), **or**
     - ii. Belinostat[2] (e.g., Beleodaq), **or**
     - iii. Sacituzumab govitecan-hziy[3] (e.g., Trodelyy).
2. UGT1A1 variant analysis to determine drug metabolizer status is considered **investigational** for all other indications.

1 Commonly prescribed for treatment if colon and rectal cancers
2 Commonly prescribed for treatment of peripheral T-cell lymphoma
3 Commonly prescribed for treatment of breast and urothelial cancers

Back to top

***UGT2B17 Variant Analysis***

1. UGT2B17 variant analysis to determine drug metabolizer status is **medically necessary** when:
   - A. The member is being considered for or is currently undergoing treatment with belzutifan[1] (e.g., Welireg).
2. UGT2B17 variant analysis to determine drug metabolizer status is considered **investigational** for all other indications.

1 Commonly prescribed to treat tumors in individuals with Von Hippel-Lindau syndrome

Back to top

***VKORC1* Variant Analysis**

1. *VKORC1* variant analysis to determine drug metabolizer status is considered **medically necessary** when:
   - A. The member is being considered for or is currently undergoing treatment with warfarin[1] (e.g., Coumadin, Jantoven).
2. *VKORC1* variant analysis to determine drug metabolizer status is considered **investigational** for all other indications.

1 Commonly prescribed to reduce the formation of blood clots

Back to top

**Warfarin Sensitivity Analysis Panels**

1. Multigene analysis to determine drug metabolizer status for warfarin[1] sensitivity is considered **medically necessary** when:
   - A. The member is being considered for or is undergoing treatment with warfarin, **and**
     - i. The member has not reached a therapeutic dose, **and**
   - B. The member is undergoing prophylaxis and treatment of venous thrombosis or pulmonary embolism, **or**
   - C. The member is undergoing prophylaxis and treatment of thromboembolic complications associated with atrial fibrillation and/or cardiac valve replacement, **or**
   - D. The member has a history of previous myocardial infarction.
2. Multigene panel analysis to confirm drug metabolizer status for warfarin[1] sensitivity is considered **investigational** for all other indications.

[1] Commonly prescribed to reduce the formation of blood clots

Back to top

**Other Pharmacogenetic Single Gene Variant Analysis**

1. Variant analysis of all other genes for drug metabolizer status is considered **investigational**, including but not limited to:
   - A. *COMT*
   - B. *CYP1A2*
   - C. *KIF6*
   - D. *OPRM1*
   - E. *TYMS*

## Products

This information is for most, but not all, HealthPartners plans. Please read your plan documents to see if your plan has limits or will not cover some items. If there is a difference between this general information and your plan documents, your plan documents will be used to determine your coverage. These coverage criteria do not apply to

Medicare Products. For more information regarding Medicare coverage criteria or for a copy of a Medicare coverage policy, contact Member Services at 952-883-7272 or 1-877-778-8384.

Approved Medical Director Committee 6/18/21; Revised 11/23/2021, 10/5/2022, 9/27/2023, 03/12/2024, 09/13/2024; 12/31/2024 Reviewed 11/2021, 7/2022, 1/2023, 7/2023, 1/2024, 7/2024, 1/2025

## References


1. Greden JF, Parikh SV, Rothschild AJ, et al. Impact of pharmacogenomics clinical outcomes major depressive disorder in the GUIDED trial: a large, patient- and rater-blinded, randomized, controlled study. J Psychiatr Res. 2019;111:59-67. doi:10.1016/j.jpsychires.2019.01.003
2. Perlis RH, Dowd D,Fava M, Lencz T, Krause DS. Randomized, controlled, participant- and rater-blind trial of pharmacogenomic test-guided treatment versus treatment as usual for major depressive disorder. Depress Anxiety. 2020;37(9): 834-841. doi:10.1002/da.23029
3. Shan X, Zhao W, Qiu Y,et al. Preliminary clinical investigation of combinatorial pharmacogenomic testing for the optimized treatment of depression: a randomized single-blind study. Front Neurosci. 2019;13:960. doi:10.3389/fnins.2019.00960
4. Tiwari AK, Zai CC, Altar CA, et al. Clinical utility of combinatorial pharmacogenomic testing in depression: a Canadian patient- and rater-blinded, randomized, controlled trial. Transl Psychiatry. 2022;12(1):101. doi:10.1038/s41398-022-01847-8
5. Oslin DW, Lynch KG, Shih MC, et al. Effect of Pharmacogenomic Testing for Drug-Gene Interactions on Medication Selection and Remission of Symptoms in Major Depressive Disorder: The PRIME Care Randomized Clinical Trial. JAMA. 2022;328(2):151-161. doi:10.1001/jama.2022.9805
6. Bunka M, Wong G, Kim D, et al. Evaluating treatment outcomes in pharmacogenomic-guided care for major depression: A rapid review and meta-analysis. Psychiatry Res. 2023;321:115102.
7. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Breast Cancer. Version 4.2024. https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf
8. Table of Pharmacogenetic Associations. (2022, October 26). FDA. https://www.fda.gov/medical-devices/precision-medicine/table-pharmacogenetic-associations. Accessed June 5, 2024.
9. Bristol-Myers Squibb Company. Coumadin (warfarin sodium). U.S. Food and Drug Administration. Website: https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/009218s107lbl.pdf. Accessed 12/5/2023.
10. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines for Oncology: Acute Lymphoblastic Leukemia. Version 2.2024. https://www.nccn.org/professionals/physician_gls/pdf/all.pdf
11. Chen LN, Carvajal RD. Tebentafusp for the treatment of HLA-A*02:01-positive adult patients with unresectable or metastatic uveal melanoma. Expert Rev Anticancer Ther. 2022 Oct;22(10):1017-1027. doi: 10.1080/14737140.2022.2124971. Epub 2022 Sep 19. PMID: 36102132; PMCID: PMC10184536.
12. Immunocore Limited. KIMMTRAK (tebentafusp-tebn) injection. U.S. Food and Drug Administration. Accessed: 5/8/2024. Website: https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/761228s000lbl.pdf
13. Minnesota statue 62Q.473 Biomarker Testing.
14. Iowa statute 514C.36 Biomarker Testing.