GENETIC TESTING: PHARMACOGENETICS

OVERVIEW

Pharmacogenetic tests are germline genetic tests that are developed to aid in assessing an individual's response to a drug treatment or to predict the risk of toxicity from a specific drug treatment. Testing may be performed prior to initiation of treatment to identify if an individual has genetic variants that could either affect response to a particular drug and/or increase the risk of adverse drug reactions. Testing may also be performed during treatment to assess an individual who has had an adverse drug reaction or to assess response to treatment. Test methodology includes genotyping and single nucleotide variant testing.

POLICY REFERENCE TABLE

The tests and associated laboratories and CPT codes contained within this document serve only as examples to help users navigate claims and corresponding coverage criteria; as such, they are not comprehensive and are not a guarantee of coverage or non-coverage. Please see the Concert Genetics Platform for a comprehensive list of registered tests.

Coverage Criteria Sections	Example Tests (Labs)	Common CPT Codes	Common ICD Codes	Ref
Pharmacogenetic Panel Tests	GeneSight Psychotropic (Myriad Genetics)	0345U	F01-F69, F80-F99, Z81.8, Z86.59	1, 2, 3, 4, 5, 6
	Professional PGX (formerly Genecept Assay) (Genomind)	81418		
	PGxOne (Admera Health)			
	Genomind Professional PGX Express CORE	0175U		
	Cytochrome P450 Genotyping Panel (ARUP	81418	I20.0, I21.01-I22.9, I24.1, I25.110, I63.50-	

	Laboratories)		I63.549 , I66.01-I66.9, I73	
	OneOme RightMed Pharmacogenomic Test (OneOme)	0347U, 0348U, 0349U, 0350U	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, T46.6X1A-T46.6X6S, Z13.71-Z13.79, Z80.3, Z81.8, Z82.49, Z85.3, Z86.000, Z86.59, Z86.71-Z86.79	
	Focused Pharmacogenomics Panel (Mayo Clinic Laboratories)	0029U	I20.0, I21.01-I22.9, I24.1, I25.110, I63.50-I63.549 , I66.01-I66.9, I73	
	Warfarin Response Genotype (Mayo Medical Laboratories)	0030U	I21.0-I22.9, I26.01-I26.99, I48.0, I60.00-I66.99, I82.210-I82.91, Z86.71-Z86.79	
	Psych HealthPGx Panel, (RPRD Diagnostics)	0173U	F01-F69, F80-F99, Z81.8, Z86.59	
	PersonalisedRX (Lab Genomics LLC)	0380U		
	Serotonin Receptor Genotype (HTR2A and HTR2C), (Mayo Medical Laboratories)	0033U		
Pharmacogenetic Single Gene Tests				
BCHE Variant Analysis	BCHE Single Gene Test (Blueprint Genetics)	81479	Z01.81, Z01.810, Z01.811, Z01.818, Z01.89	8
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-	8

			I66.99, I82.210-I82.91, Z86.71-Z86.79	
CYP2C19 Variant Analysis	CYP2C19 Single Gene Test (Blueprint Genetics)	81225	C64, F32, I21.0-I22.9, I24.9, I26.01-I26.99, I48.0, I60.00-I66.99, I82.210-I82.91, K21.9, L20, Q85.83, R56.9, R68.82, Z86.71-Z86.79	8
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	7, 8
	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 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	CYP3A5 single gene test	81231	T86, Z79.6, Z94	8

Analysis	(Blueprint Genetics)			
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	8
DPYD Variant Analysis	DPD 5-Fluorouracil Toxicity (Labcorp)	81232	C00.0-C96.9, D00.0-D49.9	8
*HLA-B**15:02 Variant Analysis	HLA-B*15:02, Carbamazepine Sensitivity (Labcorp)	81381	G40	8
*HLA-B**57:01 Variant Analysis	HLA B*57:01 Abacavir Hypersensitivity (Labcorp)	81381	B20, Z21	8
NAT2 Variant Analysis	NAT2 single gene test (Blueprint Genetics)	81479	G73, M35.9	8
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	8
	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	8
UGT2B17 Variant Analysis	UGT2B17 Single Gene (Fulgent Genetics)	81479	C25, C64, C71, C72, Q85.83	8
VKORC1 Variant Analysis	VKORC1 Single Gene Test (Blueprint Genetics)	81355	I21.0-I22.9, I26.01-I26.99, I48.0, I60.00-I66.99, I82.210-I82.91,	8

			Z86.71-Z86.79	
Other Single Gene Variant Analysis	Catechol-O-Methyltransferase (COMT) Genotype (Mayo Clinic Laboratories)	0032U	F01-F69, F80-F99, G20, Z81.8, Z86.59	8
	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	
	SLCO1B1, 1 Variant (ARUP Laboratories)	81328	E78.00-E78.5, G71.14, R79.9, T46.6X1A-T46.6X6S, Z82.49	
	TYMS Single Gene (Sequencing & Deletion/Duplication) (Fulgent Genetics)	81479	C00.0-C96.9, D00.0-D49.9	

OTHER RELATED POLICIES

This policy document provides coverage for tests that determine the dosage of or the selection of a specific drug based on pharmacogenetic testing. For other related testing, please refer to:

- ***Oncology: Molecular Analysis of Solid Tumors and Hematologic Malignancies*** for coverage criteria related to DNA testing of a solid tumor or a blood cancer.

- ***Genetic Testing: Hematologic Conditions (non-cancerous)*** for coverage criteria related to diagnostic testing for non-cancerous genetic blood disorders.
- ***Genetic Testing: Multisystem Inherited Disorders, Intellectual Disability, and Developmental Delay*** for coverage criteria related to diagnostic testing for cystic fibrosis, and related therapies.
- ***Genetic Testing: Metabolic, Endocrine, and Mitochondrial Disorders*** for coverage criteria related to *MTHFR* testing.
- ***Genetic Testing: General Approach to Genetic and Molecular Testing*** for coverage criteria related to pharmacogenetic testing that are not specifically discussed in this or other specific policies.

COVERAGE CRITERIA

PHARMACOGENETIC PANEL TESTS

I. The use of pharmacogenetic testing panels (81418, 0029U, 0030U, 0033U, 0173U, 0345U, 0347U, 0348U, 0349U, 0350U, 0380U) is considered **investigational*** for all indications.

*See *HLA-B**15:02 and *HLA-A**31:01 Variant Analysis and *TPMT* and *NUDT15* Variant Analysis below for coverage criteria. These tests involve analysis of more than one gene, but are 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

I. *BCHE* variant analysis (81479) to determine drug metabolizer status is considered **medically necessary** when:

   A. The member is being considered for or is currently undergoing treatment with mivacurium[1] (e.g., Mivacron), **OR**

   B. The member is being considered for or is currently undergoing treatment with succinylcholine[1] (e.g., Anectine, Suxamethonium)

II. *BCHE* variant analysis (81479) to determine drug metabolizer status is considered **investigational** for all other indications.

1 Commonly used as a muscle relaxant during surgery or intubation

back to top

CYP2C9 Variant Analysis

I. *CYP2C9* variant analysis (81227) to determine drug metabolizer status is considered **medically necessary** when:

A. The member is being considered for or is currently undergoing treatment with siponimod[1] (e.g., Mayzent), **OR**

B. The member is being considered for or is currently undergoing treatment with celecoxib[2] (e.g., Celebrex, Elyxyb), **OR**

C. The member is being considered for or is currently undergoing treatment with dronabinol[3] (e.g., Marinol, Syndros), **OR**

D. The member is being considered for or is currently undergoing treatment with erdafitinib[4] (e.g., Balversa), **OR**

E. The member is being considered for or is currently undergoing treatment with flurbiprofen[5] (e.g., Ansaid), **OR**

F. The member is being considered for or is currently undergoing treatment with fosphenytoin[6] (e.g., Cerebyx, Sesquient), **OR**

G. The member is being considered for or is currently undergoing treatment with meloxicam[7] (e.g., Anjeso, Mobic, Vivlodex, Qmiiz ODT), **OR**

H. The member is being considered for or is currently undergoing treatment with nateglinide[8] (e.g., Starlix), **OR**

I. The member is being considered for or is currently undergoing treatment with phenytoin[9] (e.g., Dilantin, Phenytek), **OR**

J. The member is being considered for or is currently undergoing treatment with piroxicam[10] (e.g., Feldene), **OR**

K. The member is being considered for or is currently undergoing treatment with warfarin[11] (e.g., Coumadin, Jantoven)

II. *CYP2C9* variant analysis (81227) 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

I. *CYP2C19* variant analysis (81225) to determine drug metabolizer status is considered **medically necessary** when:

A. The member is being considered for or is currently undergoing treatment with clopidogrel[1] (e.g., Plavix), **AND**

B. The member meets all of the following:

1. Will be undergoing percutaneous coronary intervention (PCI), **AND**

2. Has acute coronary syndromes (ACS), **AND**

3. Is at high risk for poor outcomes (e.g., urgent PCI for an ACS event, elective PCI for unprotected left main disease or last patent coronary artery), **OR**

C. The member is being considered for or is currenting undergoing treatment with abrocitinib[2] (e.g., Cibinqo), **OR**

D. The member is being considered for or is currenting undergoing treatment with belzutifan[3] (e.g., Welireg), **OR**

E. The member is being considered for or is currenting undergoing treatment with brivaracetam[4] (e.g., Briviact, Brivajoy), **OR**

F. The member is being considered for or is currenting undergoing treatment with citalopram[5] (e.g., Celexa), **OR**

G. The member is being considered for or is currenting undergoing treatment with clobazam[6] (e.g., Onfi) , **OR**

H. The member is being considered for or is currenting undergoing treatment with flibanserin[7] (e.g., Addyi) , **OR**

I. The member is being considered for or is currenting undergoing treatment with pantoprazole[8] (e.g., Protonix)

II. *CYP2C19* variant analysis (81225) to determine drug metabolizer status is considered **investigational** for all other indications.

1 Commonly prescribed after a 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

I. *CYP2D6* variant analysis (81226, 0070U, 0071U, 0072U, 0073U, 0074U, 0075U, 0076U) to determine drug metabolizer status is considered **medically necessary** when:

A. The member is being considered for or is currently undergoing treatment with eliglustat[1] (e.g., Cerdelga), **OR**

B. The member is being considered for or is currently undergoing treatment with tetrabenazine[2] (e.g., Xenazine), **OR,**

C. The member is being considered for or is currently undergoing treatment with amphetamine[3] (e.g., Adzenys, Dyanavel, Evekeo), **OR**

D. The member is being considered for or is currently undergoing treatment with aripiprazole[4] (e.g., Abilify, Abilify Maintena), **OR**

E. The member is being considered for or is currently undergoing treatment with aripiprazole lauroxil[5] (e.g., Aristada), **OR**

F. The member is being considered for or is currently undergoing treatment with atomoxetine[6] (e.g., Strattera), **OR**

G. The member is being considered for or is currently undergoing treatment with brexpiprazole[7] (e.g., Rexulti), **OR**

H. The member is being considered for or is currently undergoing treatment with clozapine[8] (e.g., Versacloz, FazaClo, Clozaril), **OR**

I. The member is being considered for or is currently undergoing treatment with deutetrabenazine[9] (e.g., Austedo), **OR**

J. The member is being considered for or is currently undergoing treatment with gefitinib[10] (e.g., Iressa), **OR**

K. The member is being considered for or is currently undergoing treatment with iloperidone[11] (e.g., Fanapt), **OR**

L. The member is being considered for or is currently undergoing treatment with lofexidine[12] (e.g., Lucemyra), **OR**

M. The member is being considered for or is currently undergoing treatment with meclizine[13] (e.g., Antivert, Bonine, Dramamine, Verticalm, Zentrip), **OR**

N. The member is being considered for or is currently undergoing treatment with metoclopramide[14] (e.g., Reglan), **OR**

O. The member is being considered for or is currently undergoing treatment with oliceridine[15] (e.g., Olinvyk), **OR**

P. The member is being considered for or is currently undergoing treatment with pimozide[16] (e.g., Orap), **OR**

Q. The member is being considered for or is currently undergoing treatment with pitolisant[17] (e.g., Wakix), **OR**

R. The member is being considered for or is currently undergoing treatment with propafenone[18] (e.g., Rythmol), **OR**

S. The member is being considered for or is currently undergoing treatment with thioridazine[19] (e.g., Mellaril), **OR**

T. The member is being considered for or is currently undergoing treatment with tramadol[20] (e.g., ConZip, Ultram), **OR**

U. The member is being considered for or is currently undergoing treatment with valbenazine[21] (e.g., Ingrezza), **OR**

V. The member is being considered for or is currently undergoing treatment with venlafaxine[22] (e.g., Effexor), **OR**

W. The member is being considered for or is currently undergoing treatment with vortioxetine[23] (e.g., Trintellix, Brintellix), **OR**

X. The member is being considered for or is currently undergoing treatment with codeine[24].

II. *CYP2D6* variant analysis (81226, 0070U, 0071U, 0072U, 0073U, 0074U, 0075U, 0076U) 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

I. *CYP3A5* variant analysis (81231) 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)

II. *CYP3A5* variant analysis (81231) 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

I. *CYP4F2* variant analysis (81479) 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)

II. *CYP4F2* variant analysis (81479) 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

I. *DPYD* variant analysis (81232) to determine drug metabolizer status is considered **medically necessary** when:

   A. The member is being considered for or is currently undergoing treatment with fluorouracil[1] (e.g., Adrucil), **OR**

   B. The member is being considered for or is currently undergoing treatment with capecitabine[1] (e.g., Xeloda)

II. *DPYD* variant analysis (81232) 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-B*15:02* Variant Analysis

I. *HLA-B*15:02* variant analysis (81381) to determine drug metabolizer status is considered **medically necessary** when:

A. The member is being considered for or is currently undergoing treatment with any carbamazepine containing therapy[1] (e.g., Tegretol, Carbatrol, Epitol, Equetro), **OR**

B. The member is being considered for or is currently undergoing treatment with phenytoin[2] (e.g., Dilantin, Phenytek), **OR**

C. The member is being considered for or is currently undergoing treatment with fosphenytoin[2] (e.g., Cerebyx, Sesquient)

II. *HLA-B*15:02* variant analysis (81381) 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

I. *HLA-B*57:01* variant analysis (81381) to determine drug metabolizer status is considered **medically necessary** when:

A. The member is being considered for or is currently undergoing treatment with abacavir[1] (e.g., Ziagen).

II. *HLA-B*57:01* variant analysis (81381) 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

I. *NAT2* variant analysis (81479) 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)

II. *NAT2* variant analysis (81479) 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

I. *TMPT* and *NUDT15* variant analysis (81306, 81335, 0034U, 0169U) to determine drug metabolizer status is considered **medically necessary** when:

   A. The member is being considered for or is currenting undergoing treatment with azathioprine[1] (e.g., Imuran and Azasan), **OR**

   B. The member is being considered for or is currently undergoing treatment with mercaptopurine[2] (e.g., Purinethol and Purixan), **OR**

   C. The member is being considered for or is currenting undergoing treatment with thioguanine[3] (e.g., Tabloid), **OR**

   D. The member is on thiopurine therapy and has had abnormal complete blood count results that do not respond to dose reduction.

II. *TPMT* and *NUDT15* variant analysis (81306, 81335, 0034U, 0169U) 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

I. *UGT1A1* variant analysis (81350) to determine drug metabolizer status is considered **medically necessary** when:

A. The member is being considered for or is currently undergoing treatment with irinotecan[1] (e.g., Onivyde, Camptosar), **OR**

B. The member is being considered for or is currently undergoing treatment with belinostat[2] (e.g., Beleodaq), **OR**

C. The member is being considered for or is currently undergoing treatment with sacituzumab govitecan-hziy[3] (e.g., Trodelvy)

II. *UGT1A1* variant analysis (81350) to determine drug metabolizer status is considered **investigational** for all other indications.

1 Commonly prescribed for treatment of 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

I. *UGT2B17* variant analysis (81479) 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)

II. *UGT2B17* variant analysis (81479) 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

I. *VKORC1* variant analysis (81355) 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)

II. *VKORC1* variant analysis (81355) 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

Other Single Gene Variant Analysis

I. Variant analysis of all other genes for drug metabolizer status is considered **investigational**, including but not limited to:

   A. *COMT* (0032U, 81479)
   B. *CYP1A2* (0031U, 81479)
   C. *KIF6* (81479)
   D. *OPRM1* (81479)
   E. *SLCO1B1* (81328)
   F. *TYMS* (81479)

back to top

BACKGROUND AND RATIONALE

Pharmacogenetic Panel Testing

There are no professional society guidelines that address the clinical utility of large pharmacogenetic testing panels for the general population or for a specific population.

The US Food and Drug Administration (FDA) also does not address the usage of pharmacogenetic panels.

There are several recent studies that investigated the usefulness of pharmacogenetic panels [for example, Greden et al (2019), Perlis et al (2020), Shan et al (2019), Tiwari et al (2022), Oslin (2022)]. However, these studies had different designs and often conflicting results regarding clinical utility, making it difficult to determine whether there is clinical utility for these types of tests.

A rapid review and meta-analysis by Bunka et al (2023) of 10 randomized controlled trials to evaluate pharmacogenomic-guided care for major depression showed that, while there is likely beneficial effects to adults with moderate to severe major depressive disorder utilizing pharmacogenomic panels, there is “very low certainty in the magnitude of effect.” (p. 1) This analysis also noted the “high risk of bias and inconsistency between trials.” (p. 1)

There are several single gene pharmacogenetic tests in which the FDA describes the clinical utility of the test results for a given gene/drug/testing indication. These are outlined below.

***BCHE* Variant Analysis**

Food and Drug Administration (FDA)

The FDA published a Table of Pharmacogenetic Associations, which details possible gene-drug interactions. Section 1, entitled Pharmacogenetic Associations for which the Data Support Therapeutic Management Recommendations, lists the following recommendations for *BCHE*:

Drug	Gene	Affected Subgroups	Description of Gene-Drug Interaction
Mivacurium	BCHE	intermediate or poor metabolizers	Results in higher systemic concentrations and higher adverse reaction risk (prolonged neuromuscular blockade). Avoid use in poor metabolizers.
Succinylcholine	BCHE	intermediate or poor	Results in higher systemic concentrations

		metabolizers	and higher adverse reaction risk (prolonged neuromuscular blockade). Avoid use in poor metabolizers. May administer test dose to assess sensitivity and administer cautiously via slow infusion.

CYP2C9 Variant Analysis

Food and Drug Administration (FDA)

The FDA published a Table of Pharmacogenetic Associations which details possible gene-drug interactions. Section 1, entitled Pharmacogenetic Associations for which the Data Support Therapeutic Management Recommendations, list the following recommendations for *CYP2C9*:

Drug	Gene	Affected Subgroups	Description of Gene-Drug Interaction
Celecoxib	CYP2C9	poor metabolizers or *3 carriers	Results in higher systemic concentrations. Reduce starting dose to half of the lowest recommended dose in poor metabolizers. Consider alternative therapy in poor metabolizers with juvenile rheumatoid arthritis.
Dronabinol	CYP2C9	intermediate or poor metabolizers	May result in higher systemic concentrations and higher adverse reaction risk. Monitor for adverse reactions.
Erdafitinib	CYP2C9	*3/*3 (poor metabolizers)	May result in higher systemic concentrations and higher adverse reaction risk. Monitor for adverse reactions.
Flurbiprofen	CYP2C9	poor metabolizers or *3 carriers	Results in higher systemic concentrations. Use a reduced dosage in poor metabolizers.

Fosphenytoin	CYP2C9	intermediate or poor metabolizers	May result in higher systemic concentrations and higher adverse reaction risk (central nervous system toxicity). Consider starting at the lower end of the dosage range and monitor serum concentrations. Refer to FDA labeling for specific dosing recommendations. Carriers of CYP2C9*3 alleles may be at increased risk of severe cutaneous adverse reactions. Consider avoiding fosphenytoin as an alternative to carbamazepine in patients who are CYP2C9*3 carriers. Genotyping is not a substitute for clinical vigilance and patient management.
Meloxicam	CYP2C9	poor metabolizers or *3 carriers	Results in higher systemic concentrations. Consider dose reductions in poor metabolizers. Monitor patients for adverse reactions.
Nateglinide	CYP2C9	poor metabolizers	Results in higher systemic concentrations and may result in higher adverse reaction risk (hypoglycemia). Dosage reduction is recommended. Increase monitoring frequency for adverse reactions. Refer to FDA labeling for specific dosing recommendations.
Phenytoin	CYP2C9	intermediate or poor metabolizers	May result in higher systemic concentrations and higher adverse reaction risk (central nervous system toxicity). Refer to FDA labeling for specific dosing recommendations. Carriers of CYP2C9*3 alleles may be at increased risk of severe cutaneous adverse reactions. Consider avoiding phenytoin as an alternative to carbamazepine in patients who are CYP2C9*3 carriers. Genotyping is not a substitute for clinical

			vigilance and patient management.
Piroxicam	CYP2C9	intermediate or poor metabolizers	Results in higher systemic concentrations. Consider reducing dosage in poor metabolizers.
Siponimod	CYP2C9	intermediate or poor metabolizers	Results in higher systemic concentrations. Adjust dosage based on genotype. Do not use in patients with CYP2C9 *3/*3 genotype. Refer to FDA labeling for specific dosing recommendations.
Warfarin	CYP2C9	intermediate or poor metabolizers	Alters systemic concentrations and dosage requirements. Select initial dosage, taking into account clinical and genetic factors. Monitor and adjust dosages based on INR.

CYP2C19 Variant Analysis

Food and Drug Administration (FDA)

The FDA published a Table of Pharmacogenetic Associations which details possible gene-drug interactions. Section 1, entitled Pharmacogenetic Associations for which the Data Support Therapeutic Management Recommendations, list the following recommendations for *CYP2C19*:

Drug	Gene	Affected Subgroups	Description of Gene-Drug Interaction
Abrocitinib	CYP2C19	poor metabolizers	Results in higher systemic concentrations and may result in higher adverse reaction risk. Dosage adjustment is recommended. Refer to FDA labeling for specific dosing recommendations.
Belzutifan	CYP2C19	poor metabolizers	Results in higher systemic

	and/or UGT2B17		concentrations and may result in higher adverse reaction risk (anemia, hypoxia). Monitor patients who are poor metabolizers for both genes for adverse reactions.
Brivaracetam	CYP2C19	intermediate or poor metabolizers	Results in higher systemic concentrations and higher adverse reaction risk. Consider dosage reductions in poor metabolizers.
Citalopram	CYP2C19	poor metabolizers	Results in higher systemic concentrations and adverse reaction risk (QT prolongation). The maximum recommended dose is 20 mg.
Clobazam	CYP2C19	intermediate or poor metabolizers	Results in higher systemic active metabolite concentrations. Poor metabolism results in higher adverse reaction risk. Dosage adjustment is recommended. Refer to FDA labeling for specific dosing recommendations.
Clopidogrel	CYP2C19	intermediate or poor metabolizers	Results in lower systemic active metabolite concentrations, lower antiplatelet response, and may result in higher cardiovascular risk. Consider use of another platelet P2Y12 inhibitor.
Flibanserin	CYP2C19	poor metabolizers	May result in higher systemic concentrations and higher adverse reaction risk. Monitor patients for adverse reactions.
Pantoprazole	CYP2C19	intermediate or poor metabolizers	Results in higher systemic concentrations. Consider dosage reduction in children who are poor metabolizers. No dosage adjustment is needed for adult patients who are intermediate or poor metabolizers.

***CYP2D6* Variant Analysis**

National Comprehensive Cancer Network (NCCN)

NCCN breast cancer guidelines (4.2023) recommend against *CYP2D6* genotype testing for women being considered for tamoxifen treatment. (p. DCIS-2 and p. BINV-K)

Food and Drug Administration (FDA)

The FDA published a Table of Pharmacogenetic Associations which details possible gene-drug interactions. Section 1, entitled Pharmacogenetic Associations for which the Data Support Therapeutic Management Recommendations, list the following recommendations for *CYP2D6*:

Drug	Gene	Affected Subgroups	Description of Gene-Drug Interaction
Amphetamine	CYP2D6	poor metabolizers	May affect systemic concentrations and adverse reaction risk. Consider lower starting dosage or use alternative agent.
Aripiprazole	CYP2D6	poor metabolizers	Results in higher systemic concentrations and higher adverse reaction risk. Dosage adjustment is recommended. Refer to FDA labeling for specific dosing recommendations.
Aripiprazole Lauroxil	CYP2D6	poor metabolizers	Results in higher systemic concentrations. Dosage adjustment is recommended. Refer to FDA labeling for specific dosing recommendations.
Atomoxetine	CYP2D6	poor metabolizers	Results in higher systemic concentrations and higher adverse reaction risk. Adjust titration interval and increase dosage if tolerated. Refer to FDA labeling for specific dosing recommendations.

Brexpiprazole	CYP2D6	poor metabolizers	Results in higher systemic concentrations. Dosage adjustment is recommended. Refer to FDA labeling for specific dosing recommendations.
Clozapine	CYP2D6	poor metabolizers	Results in higher systemic concentrations. Dosage reductions may be necessary.
Codeine	CYP2D6	ultrarapid metabolizers	Results in higher systemic active metabolite concentrations and higher adverse reaction risk (life-threatening respiratory depression and death). Codeine is contraindicated in children under 12 years of age.
Deutetrabenazine	CYP2D6	poor metabolizers	Results in higher systemic concentrations and adverse reaction risk (QT prolongation). The maximum recommended dosage should not exceed 36 mg (maximum single dose of 18 mg).
Eliglustat	CYP2D6	ultrarapid, normal, intermediate, or poor metabolizers	Alters systemic concentrations, effectiveness, and adverse reaction risk (QT prolongation). Indicated for normal, intermediate, and poor metabolizer patients. Ultrarapid metabolizers may not achieve adequate concentrations to achieve a therapeutic effect. The recommended dosages are based on CYP2D6 metabolizer status. Coadministration with strong CYP3A inhibitors is contraindicated in intermediate and poor CYP2D6 metabolizers. Refer to FDA labeling for specific dosing recommendations.

Gefitinib	CYP2D6	poor metabolizers	Results in higher systemic concentrations and higher adverse reaction risk. Monitor for adverse reactions.
Iloperidone	CYP2D6	poor metabolizers	Results in higher systemic concentrations and higher adverse reaction risk (QT prolongation). Reduce dosage by 50%.
Lofexidine	CYP2D6	poor metabolizers	Results in higher systemic concentrations and higher adverse reaction risk. Monitor for orthostatic hypotension and bradycardia.
Meclizine	CYP2D6	ultrarapid, intermediate, or poor metabolizers	May affect systemic concentrations. Monitor for adverse reactions and clinical effect.
Metoclopramide	CYP2D6	poor metabolizers	Results in higher systemic concentrations and higher adverse reaction risk. The recommended dosage is lower. Refer to FDA labeling for specific dosing recommendations.
Oliceridine	CYP2D6	poor metabolizers	Results in higher systemic concentrations and higher adverse reaction risk (respiratory depression and sedation). May require less frequent dosing.
Pimozide	CYP2D6	poor metabolizers	Results in higher systemic concentrations. Dosages should not exceed 0.05 mg/kg in children or 4 mg/day in adults who are poor metabolizers and dosages should not be increased earlier than 14 days.

Pitolisant	CYP2D6	poor metabolizers	Results in higher systemic concentrations. Use lowest recommended starting dosage. Refer to FDA labeling for specific dosing recommendations.
Propafenone	CYP2D6	poor metabolizers	Results in higher systemic concentrations and higher adverse reaction risk (arrhythmia). Avoid use in poor metabolizers taking a CYP3A4 inhibitor.
Tetrabenazine	CYP2D6	poor metabolizers	Results in higher systemic concentrations. The maximum recommended single dose is 25 mg and should not exceed 50 mg/day.
Thioridazine	CYP2D6	poor metabolizers	Results in higher systemic concentrations and higher adverse reaction risk (QT prolongation). Predicted effect based on experience with CYP2D6 inhibitors. Contraindicated in poor metabolizers.
Tramadol	CYP2D6	Ultrarapid metabolizers	Results in higher systemic and breast milk active metabolite concentrations, which may result in respiratory depression and death. Contraindicated in children under 12 and in adolescents following tonsillectomy/adenoidectomy. Breastfeeding is not recommended during treatment.
Valbenazine	CYP2D6	poor metabolizers	Results in higher systemic active metabolite concentrations and higher adverse reaction risk (QT prolongation). Dosage reductions may be necessary.

Venlafaxine	CYP2D6	poor metabolizers	Alters systemic parent drug and metabolite concentrations. Consider dosage reductions.
Vortioxetine	CYP2D6	poor metabolizers	Results in higher systemic concentrations. The maximum recommended dose is 10 mg.

CYP3A5 Variant Analysis

Food and Drug Administration (FDA)

The FDA published a Table of Pharmacogenetic Associations, which details possible gene-drug interactions. Section 1, entitled Pharmacogenetic Associations for which the Data Support Therapeutic Management Recommendations, lists the following recommendations for *CYP3A5*:

Drug	Gene	Affected Subgroups	Description of Gene-Drug Interaction
Tacrolimus	CYP3A5	intermediate or normal metabolizers	Results in lower systemic concentrations, lower probability of achieving target concentrations and may result in higher rejection risk. Measure drug concentrations and adjust dosage based on trough whole blood tacrolimus concentrations.

CYP4F2 Variant Analysis

Food and Drug Administration (FDA)

The FDA published a Table of Pharmacogenetic Associations which details possible gene-drug interactions. Section 1, entitled Pharmacogenetic Associations for which the Data Support Therapeutic Management Recommendations, list the following recommendations for *CYP4F2*:

Drug	Gene	Affected Subgroups	Description of Gene-Drug Interaction
Warfarin	CYP4F2	V433M variant carriers	May affect dosage requirements. Monitor and adjust doses based on INR.

DPYD Variant Analysis

Food and Drug Administration (FDA)

The FDA published a Table of Pharmacogenetic Associations which details possible gene-drug interactions. Section 1, entitled Pharmacogenetic Associations for which the Data Support Therapeutic Management Recommendations, list the following recommendations for *DPYD*:

Drug	Gene	Affected Subgroups	Description of Gene-Drug Interaction
Capecitabine	DPYD	intermediate or poor metabolizers	Results in higher adverse reaction risk (severe, life-threatening, or fatal toxicities). No dosage has proven safe in poor metabolizers, and insufficient data are available to recommend a dosage in intermediate metabolizers. Withhold or discontinue in the presence of early-onset or unusually severe toxicity.
Fluorouracil	DPYD	intermediate or poor metabolizer	Results in higher adverse reaction risk (severe, life-threatening, or fatal toxicities). No dosage has proven safe in poor metabolizers and insufficient data are available to recommend a dosage in intermediate metabolizers. Withhold or discontinue in the presence of early-onset or unusually severe toxicity.

HLA-B*15:02 Variant Analysis

Food and Drug Administration (FDA)

The FDA published a Table of Pharmacogenetic Associations which details possible gene-drug interactions. Section 1, entitled Pharmacogenetic Associations for which the Data Support Therapeutic Management Recommendations, list the following recommendations for HLA-B*15:02:

Drug	Gene	Affected Subgroups	Description of Gene-Drug Interaction
Carbamazepine	HLA-B	*15:02 allele positive	Results in higher adverse reaction risk (severe skin reactions). Avoid use unless potential benefits outweigh risks and consider risks of alternative therapies. Patients positive for HLA-B*15:02 may be at increased risk of severe skin reactions with other drugs that are associated with a risk of Stevens Johnson Syndrome/Toxic Epidermal necrolysis (SJS/TEN). Genotyping is not a substitute for clinical vigilance.
Fosphenytoin	HLA-B	*15:02 allele positive	May result in higher adverse reaction risk (severe cutaneous reactions). Patients positive for HLA-B*15:02 may be at increased risk of Stevens Johnson Syndrome/Toxic Epidermal necrolysis (SJS/TEN). Consider avoiding fosphenytoin as an alternative to carbamazepine in patients who are positive for HLA-B*15:02. Genotyping is not a substitute for clinical vigilance and patient management.
Phenytoin	HLA-B	*15:02 allele positive	May result in higher adverse reaction risk (severe cutaneous reactions). Patients positive for HLA-B*15:02 may be at increased risk of Stevens Johnson Syndrome/Toxic Epidermal necrolysis (SJS/TEN). Consider avoiding phenytoin as an alternative to carbamazepine in patients who are positive for HLA-B*15:02. Genotyping is not a substitute for clinical vigilance and patient management.

HLA-B*57:01 Variant Analysis

Food and Drug Administration (FDA)

The FDA published a Table of Pharmacogenetic Associations which details possible gene-drug interactions. Section 1, entitled Pharmacogenetic Associations for which the Data Support Therapeutic Management Recommendations, list the following recommendations for HLA-B*57:01:

Drug	Gene	Affected Subgroups	Description of Gene-Drug Interaction
Abacavir	HLA-B	*57:01 allele positive	Results in higher adverse reaction risk (hypersensitivity reactions). Do not use abacavir in patients positive for HLA-B*57:01.

NAT2 Variant Analysis

Food and Drug Administration (FDA)

The FDA published a Table of Pharmacogenetic Associations, which details possible gene-drug interactions. Section 1, entitled Pharmacogenetic Associations for which the Data Support Therapeutic Management Recommendations, lists the following recommendations for *NAT2*:

Drug	Gene	Affected Subgroups	Description of Gene-Drug Interaction
Amifampridine	NAT2	poor metabolizers	Results in higher systemic concentrations and higher adverse reaction risk. Use lowest recommended starting dosage and monitor for adverse reactions. Refer to FDA labeling for specific dosing recommendations.
Amifampridine Phosphate	NAT2	poor metabolizers	Results in higher systemic concentrations. Use lowest recommended starting dosage (15 mg/day) and monitor for adverse reactions.

TPMT and *NUDT15* Variant Analysis

Food and Drug Administration (FDA)

The FDA published a Table of Pharmacogenetic Associations which details possible gene-drug interactions. Section 1, entitled Pharmacogenetic Associations for which the Data Support Therapeutic Management Recommendations, list the following recommendations for *TPMT* and *NUDT15*:

Drug	Gene	Affected Subgroups	Description of Gene-Drug Interaction
Azathioprine	TPMT and/or NUDT15	intermediate or poor metabolizers	Alters systemic active metabolite concentration and dosage requirements. Results in higher adverse reaction risk (myelosuppression). Consider alternative therapy in poor metabolizers. Dosage reduction is recommended in intermediate metabolizers for NUDT15 or TPMT. Intermediate metabolizers for both genes may require more substantial dosage reductions. Refer to FDA labeling for specific dosing recommendations.
Mercaptopurine	TPMT and/or NUDT15	intermediate or poor metabolizers	Alters systemic active metabolite concentration and dosage requirements. Results in higher adverse reaction risk (myelosuppression). Initial dosages should be reduced in poor metabolizers; poor metabolizers generally tolerate 10% or less of the

			recommended dosage. Intermediate metabolizers may require dosage reductions based on tolerability. Intermediate metabolizers for both genes may require more substantial dosage reductions. Refer to FDA labeling for specific dosing recommendations.
Thioguanine	TPMT and/or NUDT15	intermediate or poor metabolizers	Alters systemic active metabolite concentration and dosage requirements. Results in higher adverse reaction risk (myelosuppression). Initial dosages should be reduced in poor metabolizers; poor metabolizers generally tolerate 10% or less of the recommended dosage. Intermediate metabolizers may require dosage reductions based on tolerability. Intermediate metabolizers for both genes may require more substantial dosage reductions. Refer to FDA labeling for specific dosing recommendations.

***UGT1A1* Variant Analysis**

Food and Drug Administration (FDA)

The FDA published a Table of Pharmacogenetic Associations which details possible gene-drug interactions. Section 1, entitled Pharmacogenetic Associations for which the Data Support Therapeutic Management Recommendations, list the following recommendations for *UGT1A1*:

Drug	Gene	Affected Subgroups	Description of Gene-Drug Interaction
Belinostat	UGT1A1	*28/*28 (poor metabolizers)	May result in higher systemic concentrations and higher adverse reaction risk. Reduce starting dose to 750 mg/m2 in poor metabolizers.
Irinotecan	UGT1A1	*1/*6, *1/*28 (intermediate metabolizers) or *6/*6, *6/*28, *28/*28 (poor metabolizers)	Results in higher systemic active metabolite concentrations and higher adverse reaction risk (severe or life-threatening neutropenia, severe diarrhea). Closely monitor for neutropenia during and after treatment. Consider reducing the starting dosage by at least one level in poor metabolizers and modify the dosage based on individual patient tolerance. Refer to FDA labeling for specific dosing recommendations.
Sacituzumab Govitecan-hziy	UGT1A1	*28/*28 (poor metabolizers)	May result in higher systemic concentrations and adverse reaction risk (neutropenia). Monitor for adverse reactions and tolerance to treatment.

UGT2B17 Variant Analysis

Food and Drug Administration (FDA)

The FDA published a Table of Pharmacogenetic Associations, which details possible gene-drug interactions. Section 1, entitled Pharmacogenetic Associations for which the Data Support Therapeutic Management Recommendations, lists the following recommendations for *UGT2B17*:

Drug	Gene	Affected Subgroups	Description of Gene-Drug Interaction
Belzutifan	CYP2C19 and/or UGT2B17	poor metabolizers	Results in higher systemic concentrations and may result in higher adverse reaction risk (anemia, hypoxia). Monitor patients who are poor metabolizers for both genes for

			adverse reactions.

VKORC1 Variant Analysis

Food and Drug Administration (FDA)

The FDA published a Table of Pharmacogenetic Associations which details possible gene-drug interactions. Section 1, entitled Pharmacogenetic Associations for which the Data Support Therapeutic Management Recommendations, list the following recommendations for *VKORC1*:

Drug	Gene	Affected Subgroups	Description of Gene-Drug Interaction
Warfarin	VKORC1	-1639G>A variant carriers	Alters dosage requirements. Select initial dosage, taking into account clinical and genetic factors. Monitor and adjust dosages based on INR.

Other Single Gene Variant Analysis

The Food and Drug Administration (FDA) does not list *COMT, CYP1A2, KIF6, OPRM1, SLCO1B1,* or *TYMS* in Section 1 of the Table of Pharmacogenetic Associations ("Pharmacogenetic Associations for which the Data Support Therapeutic Management Recommendations").

back to top

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back to top