Article - Billing and Coding: MolDX: Pharmacogenomics Testing (A57385)

Links in PDF documents are not guaranteed to work. To follow a web link, please use the MCD Website.

Contractor Information

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATES
Noridian Healthcare Solutions, LLC	A and B MAC	02101 - MAC A	J - F	Alaska
Noridian Healthcare Solutions, LLC	A and B MAC	02102 - MAC B	J - F	Alaska
Noridian Healthcare Solutions, LLC	A and B MAC	02201 - MAC A	J - F	Idaho
Noridian Healthcare Solutions, LLC	A and B MAC	02202 - MAC B	J - F	Idaho
Noridian Healthcare Solutions, LLC	A and B MAC	02301 - MAC A	J - F	Oregon
Noridian Healthcare Solutions, LLC	A and B MAC	02302 - MAC B	J - F	Oregon
Noridian Healthcare Solutions, LLC	A and B MAC	02401 - MAC A	J - F	Washington
Noridian Healthcare Solutions, LLC	A and B MAC	02402 - MAC B	J - F	Washington
Noridian Healthcare Solutions, LLC	A and B MAC	03101 - MAC A	J - F	Arizona
Noridian Healthcare Solutions, LLC	A and B MAC	03102 - MAC B	J - F	Arizona
Noridian Healthcare Solutions, LLC	A and B MAC	03201 - MAC A	J - F	Montana
Noridian Healthcare Solutions, LLC	A and B MAC	03202 - MAC B	J - F	Montana
Noridian Healthcare Solutions, LLC	A and B MAC	03301 - MAC A	J - F	North Dakota
Noridian Healthcare Solutions, LLC	A and B MAC	03302 - MAC B	J - F	North Dakota
Noridian Healthcare Solutions, LLC	A and B MAC	03401 - MAC A	J - F	South Dakota
Noridian Healthcare Solutions, LLC	A and B MAC	03402 - MAC B	J - F	South Dakota
Noridian Healthcare Solutions, LLC	A and B MAC	03501 - MAC A	J - F	Utah
Noridian Healthcare Solutions, LLC	A and B MAC	03502 - MAC B	J - F	Utah
Noridian Healthcare Solutions, LLC	A and B MAC	03601 - MAC A	J - F	Wyoming
Noridian Healthcare Solutions, LLC	A and B MAC	03602 - MAC B	J - F	Wyoming

Article Information

General Information

Article ID

A57385

Article Title

AMA CPT / ADA CDT / AHA NUBC Copyright Statement

Billing and Coding: MolDX: Pharmacogenomics Testing

Article Type
Billing and Coding

Original Effective Date
08/17/2020

Revision Effective Date
01/01/2023

Revision Ending Date
N/A

Retirement Date
N/A

CMS National Coverage Policy

Title XVIII of the Social Security Act, §1833(e), prohibits Medicare payment for any claim lacking the necessary documentation to process the claim.

Article Guidance

Article Text

The information in this article contains billing, coding or other guidelines that complement the Local Coverage Determination (LCD) for MolDX: Pharmacogenomics Testing L38337

Relevant National Coverage Determinations (NCDs):

- NCD 90:1: Testing for CYP2C9 and VKORC1 for Warfarin dosage must adhere to the requirements set forth in this NCD.

Relevant Articles:

- Billing and Coding: MolDX: Testing of Multiple Genes A58121

- Billing and Coding: MolDX: Repeat Germline Testing A57332

Additional documentation requirements for coverage and billing:

Performing providers are required to acquire and retain records of the drugs under consideration for use or in use by the ordering physician that necessitate the use of ordered test.

MolDX may make available specific forms to assist with test Technical Assessments (TAs). Please follow the instructions on the MolDX website to assist with this process. If such forms are available that pertain to the test type in question, these forms are required for successful coverage determinations.

Billing instructions:

To report a pharmacogenomics testing service, please submit the following claim information:

- Select the appropriate CPT® code
- Enter 1 unit of service (UOS)
- Enter the appropriate DEX Z-Code™ identifier adjacent to the CPT code in the comment/narrative field for the following Part B claim field/types:
    - Loop 2400 or SV101-7 for the 5010A1 837P
    - Item 19 for paper claim
- Enter the appropriate DEX Z-Code™ identifier adjacent to the CPT code in the comment/narrative field for the following Part A claim field/types:
    - Line SV202-7 for 837I electronic claim
    - Block 80 for the UB04 claim form
- Select the appropriate ICD-10-CM code

For part B claims, the drug or drugs in consideration for use that require the use of the pharmacogenomics (PGx) test must be submitted in the applicable detail line 2400 loop. If multiple drugs are being used/considered for the specified beneficiary on the claim, they should be added to the comment line separated by a "/" (example Drug 1/Drug 2). Do not list the same drug more than once. The use of the generic name is strongly preferred.

Only one test may be performed per date of service; the test should be the most likely to identify the necessary alleles/variants for the drug/drugs in question. This applies to both single gene tests and multigene panels.

The medical necessity for the additional testing and the clinical decision making for the additional testing must be documented in the medical record. The CPT code set relevant to this policy is listed in the table below. If no CPT code is available for the gene being tested, the NOC code 81479 may be used. The identification of the proper recommended billing code is established as part of the test application process.

Gene/CPT coding/Drug information

Table 1 represents relevant gene/drug associations from CPIC and FDA sources.

Table 1. Current CPIC guidelines as of March 26, 2021 and Table of Pharmacogenomic Associations from the FDA for which the data support therapeutic recommendations or a potential impact on safety or responses as of November 08, 2021.

Gene	CPT Code(s)	Generic Name	Trade Name(s)	Intended use for Drug(s)	Guidance
BCHE	81479	mivacurium, succinylcholine	Mivacurium chloride, Anectine	Neuromuscular blocking agent	FDA
CACNA1S	81479	desflurane, enflurane, halothane, isoflurane, methoxyflurane, sevoflurane, succinylcholine	Suprane, Ethrane, Fluothane, Forane, Penthrox, Ultane, Anectine, Quelicin	Volatile anesthetic	CPIC
CFTR	81220	ivacaftor	Kalydeco	Cystic fibrosis	CPIC
CYP2B6	81479	efavirenz	Sustiva	Antiretroviral; HIV	CPIC/FDA
CYP2C19	81225	brivaracetam, clobazam	Briviact, Onfi	Anticonvulsant	FDA
CYP2C19	81225	citalopram, escitalopram, sertraline	Celexa, Lexapro, Zoloft	Antidepressant - Selective Serotonin Reuptake Inhibitor (SSRI)	CPIC/FDA
CYP2C19	81225	amitriptyline, clomipramine, doxepin, imipramine, trimipramine	Elavil, Anafranil, Silenor, Tofranil, Surmontil	Antidepressant - Tricyclic	CPIC
CYP2C19	81225	voriconazole	Vfend	Antifungal	CPIC/FDA
CYP2C19	81225	flibanserin	Addyi	Mixed serotonin agonist	FDA
CYP2C19	81225	clopidogrel	Plavix	Platelet aggregation inhibitor	CPIC/FDA
CYP2C19	81225	dexlansoprazole, lansoprazole,	Dexilant, Prevacid, Prilosec, Protonix	Proton Pump Inhibitor (PPI)	CPIC/FDA

		omeprazole, pantoprazole			
CYP2C9	81227	warfarin	Jantoven, Coumadin	Anticoagulant	CPIC/FDA
CYP2C9	81227	fosphenytoin, phenytoin	Cerebyx, Dilantin	Anticonvulsant	CPIC/FDA
CYP2C9	81227	dronabinol	Marinol, Syndros	Antiemetic	FDA
CYP2C9	81227	erdafitinib	Balversa	FGFR kinase inhibitor, bladder cancer	FDA
CYP2C9	81227	siponimod	Mayzent	Multiple sclerosis	FDA
CYP2C9	81227	celecoxib, flurbiprofen, lornoxicam, meloxicam, piroxicam, tenoxicam	Celebrex, Ansaid, Ocufen, Chlortenoxicam, Xefo, Mobic, Vivlodex, Anjeso, Qmiiz ODT, Feldene, Mobiflex	Non-steroidal anti-inflammatory (NSAID)	CPIC/FDA
CYP2D6	81226, 0070U, 0071U, 0072U, 0073U, 0074U, 0075U, 0076U	carvedilol	Coreg	Alpha - Beta blocker	FDA
CYP2D6	81226, 0070U, 0071U, 0072U, 0073U, 0074U, 0075U, 0076U	propafenone	Rythmol	Antiarrhythmic	FDA
CYP2D6	81226, 0070U, 0071U, 0072U, 0073U, 0074U, 0075U, 0076U	fluvoxamine, paroxetine, venlafaxine, vortioxetine	Luvox, Paxil, Effexor XR, Brintellix, Trintellix	Antidepressant – Selective Serotonin Reuptake Inhibitor (SSRI)	CPIC/FDA
CYP2D6	81226, 0070U, 0071U, 0072U,	amitriptyline, clomipramine, desipramine,	Elavil, Anafranil, Norpramin, Silenor, Tofranil, Aventyl,	Antidepressant - Tricyclic	CPIC

	0073U, 0074U, 0075U, 0076U	doxepin, imipramine, nortriptyline, trimipramine	Pamelor, Surmontil		
CYP2D6	81226, 0070U, 0071U, 0072U, 0073U, 0074U, 0075U, 0076U	meclizine, ondansetron, tropisetron	Antivert, Zofran ODT, Tropisetron	Antiemetic	CPIC/FDA
CYP2D6	81226, 0070U, 0071U, 0072U, 0073U, 0074U, 0075U, 0076U	gefitinib, tamoxifen	Iressa, Soltamox, Nolvadex	Antineoplastic	CPIC/FDA
CYP2D6	81226, 0070U, 0071U, 0072U, 0073U, 0074U, 0075U, 0076U	aripiprazole, aripiprazole lauroxil, brexpiprazole, clozapine, iloperidone, perphenazine, pimozide, thioridazine	Abilify, Aristada, Rexulti, Clozaril, FazaClo, Versacloz, Fanapt, Trilafon, Orap, Mellaril	Antipsychotic	FDA
CYP2D6	81226, 0070U, 0071U, 0072U, 0073U, 0074U, 0075U, 0076U	amphetamine, atomoxetine	Adzenys ER, Dyanavel XR, Adderall, Strattera	Attention Deficit - Hyperactivity (ADHD) Therapy	CPIC/FDA
CYP2D6	81226, 0070U, 0071U, 0072U, 0073U, 0074U, 0075U, 0076U	metoclopramide	Reglan	Gastrointestinal prokinetic agent	FDA
CYP2D6	81226, 0070U, 0071U, 0072U, 0073U, 0074U, 0075U, 0076U	eliglustat	Cerdelga	Gaucher's disease	FDA

CYP2D6	81226, 0070U, 0071U, 0072U, 0073U, 0074U, 0075U, 0076U	deutetrabenazine, tetrabenazine	Austedo, Xenazine	Movement disorder therapy	FDA
CYP2D6	81226, 0070U, 0071U, 0072U, 0073U, 0074U, 0075U, 0076U	pitolisant	Wakix	Narcolepsy therapy agent	FDA
CYP2D6	81226, 0070U, 0071U, 0072U, 0073U, 0074U, 0075U, 0076U	codeine, oliceridine, tramadol	Olinvyk, Ultram	Opioid	CPIC/FDA
CYP2D6	81226, 0070U, 0071U, 0072U, 0073U, 0074U, 0075U, 0076U	lofexidine	Lucemyra	Opioid withdrawal	FDA
CYP2D6	81226, 0070U, 0071U, 0072U, 0073U, 0074U, 0075U, 0076U	cevimeline	Evoxac	Saliva stimulant	FDA
CYP2D6	81226, 0070U, 0071U, 0072U, 0073U, 0074U, 0075U, 0076U	tolterodine	Detrol	Urinary antispasmodic	FDA
CYP2D6	81226, 0070U, 0071U, 0072U, 0073U, 0074U, 0075U, 0076U	valbenazine	Ingrezza	VMAT2 inhibitor	FDA

CYP3A5	81231	tacrolimus	Prograf	Antirejection	CPIC/FDA
CYP4F2	81479	warfarin	Jantoven, Coumadin	Anticoagulant	CPIC/FDA
DPYD	81232	capecitabine, fluorouracil	Xeloda, Adrucil, Efudex, Fluoroplex, Tolak	Antineoplastic	CPIC/FDA
G6PD	81247	rasburicase	Elitek	Hyperuricemia	CPIC
HLA - A	81381, 81374	carbamazepine	Tegretol	Anticonvulsant	CPIC/FDA
HLA-A	81381	tebentafusp	Kimmtrak	antineoplastic	FDA
HLA - B	81381, 81374	carbamazepine, fosphenytoin, oxcarbazepine, phenytoin	Tegretol, Cerebyx, Trileptal, Dilantin	Anticonvulsant	CPIC/FDA
HLA - B	81381, 81374	pazopanib	Votrient	Antineoplastic	FDA
HLA - B	81381, 81374	abacavir	Ziagen	Antiretroviral; HIV	CPIC/FDA
HLA - B	81381, 81374	allopurinol	Aloprim, Zyloprim	Hyperuricemia	CPIC/FDA
HLA - DQA1	81377, 81383	lapatinib	Tykerb	Antineoplastic	FDA
HLA - DRB1	81377, 81383	lapatinib	Tykerb	Antineoplastic	FDA
IFNL3	81283	peginterferon alfa - 2a, peginterferon alfa - 2b	Pegasys, Pegasys ProClick, PegIntron, Sylatron	Antiviral, HCV	CPIC
NAT2	81479	procainamide	Procan, Pronestyl	Antiarrhythmic	FDA
NAT2	81479	sulfamethoxazole / trimethoprim	Bactrim	Antibacterial	FDA
NAT2	81479	isoniazid	Niazid	Antitubercular	FDA
NAT2	81479	sulfasalazine	Azulfidine	Disease-Modifying Antirheumatic	FDA

				Drug (DMARD): Other - inflammatory bowel agent	
NAT2	81479	amifampridine, amifampridine phosphate	Ruzurgi, Firdapse	Multiple sclerosis	FDA
NUDT15	81306	azathioprine, mercaptopurine, thioguanine	Azasan, Purixan, Tabloid	Antineoplastic	CPIC/FDA
RYR1	81406	desflurane, enflurane, halothane, isoflurane, methoxyflurane, sevoflurane, succinylcholine	Suprane, Ethrane, Fluothane, Forane, Penthrox, Ultane, Anectine, Quelicin	Volatile anesthetic	CPIC
SLCO1B1	81328	simvastatin	FloLipid, Zocor	Antihyperlipidemic	CPIC/FDA
TPMT	81335, 0034U, 0286U	azathioprine, mercaptopurine, thioguanine	Azasan, Purixan, Tabloid	Antineoplastic	CPIC/FDA
UGT1A1	81350	belinostat, irinotecan, nilotinib, pazopanib, Sacituzumab Govitecan - hziy	Beleodaq, Camptosar, Tasigna, Votrient, Trodelvy	Antineoplastic	FDA
UGT1A1	81350	atazanavir	Reyataz	Antiretroviral, HIV	CPIC
VKORC1	81355	warfarin	Jantoven, Coumadin	Anticoagulant	CPIC/FDA

Covered multigene panels with intended uses

Table 2 represents covered multigene panels with specified uses that have successfully completed a TA. These tests must fulfill all the criteria above and may be further limited to specific indications listed by ICD-10 codes, when applicable.

Test Name	**Company**	**Intended Use**
Genesight	Assurex Health	Major Depressive Disorder (MDD) or

		Neuropsychiatric
Genomind Professional PGx Express™	Genomind, Inc.	Neuropsychiatric
NeuroIDgenetix	AltheaDx	Major Depressive Disorder (MDD) or Neuropsychiatric
Neuropharmagen	Precision Molecular Solutions	Neuropsychiatric
Psychotropic Pharmacogenomics Gene Panel	Mayo Clinic Laboratories	Neuropsychiatric

ICD-10 codes associated with intended uses

Intended Use	**ICD-10 codes**	**Description**
MDD	F32.1	Major depressive disorder, single episode, moderate
MDD	F32.2	Major depressive disorder, single episode, severe without psychotic features
MDD	F32.3	Major depressive disorder, single episode, severe with psychotic features
MDD	F32.4	Major depressive disorder, single episode, in partial remission
MDD	F33.1	Major depressive disorder, recurrent, moderate
MDD	F33.2	Major depressive disorder, recurrent severe without psychotic features
MDD	F33.3	Major depressive disorder, recurrent, severe with psychotic symptoms
MDD	F33.41	Major depressive disorder, recurrent, in partial remission

Neuropsychiatric	F20.0	Paranoid schizophrenia
Neuropsychiatric	F20.1	Disorganized schizophrenia
Neuropsychiatric	F20.2	Catatonic schizophrenia
Neuropsychiatric	F20.3	Undifferentiated schizophrenia
Neuropsychiatric	F20.5	Residual schizophrenia
Neuropsychiatric	F20.81	Schizophreniform disorder
Neuropsychiatric	F20.89	Other schizophrenia
Neuropsychiatric	F31.0	Bipolar disorder, current episode hypomanic
Neuropsychiatric	F31.11	Bipolar disorder, current episode manic without psychotic features, mild
Neuropsychiatric	F31.12	Bipolar disorder, current episode manic without psychotic features, moderate
Neuropsychiatric	F31.13	Bipolar disorder, current episode manic without psychotic features, severe
Neuropsychiatric	F31.2	Bipolar disorder, current episode manic severe with psychotic features
Neuropsychiatric	F31.31	Bipolar disorder, current episode depressed, mild
Neuropsychiatric	F31.32	Bipolar disorder, current episode depressed, moderate
Neuropsychiatric	F31.4	Bipolar disorder, current episode depressed, severe, without psychotic features
Neuropsychiatric	F31.5	Bipolar disorder, current episode depressed, severe, with psychotic features

Neuropsychiatric	F31.61	Bipolar disorder, current episode mixed, mild
Neuropsychiatric	F31.62	Bipolar disorder, current episode mixed, moderate
Neuropsychiatric	F31.63	Bipolar disorder, current episode mixed, severe, without psychotic features
Neuropsychiatric	F31.64	Bipolar disorder, current episode mixed, severe, with psychotic features
Neuropsychiatric	F31.71	Bipolar disorder, in partial remission, most recent episode hypomanic
Neuropsychiatric	F31.73	Bipolar disorder, in partial remission, most recent episode manic
Neuropsychiatric	F31.75	Bipolar disorder, in partial remission, most recent episode depressed
Neuropsychiatric	F31.77	Bipolar disorder, in partial remission, most recent episode mixed
Neuropsychiatric	F40.11	Social phobia, generalized
Neuropsychiatric	F41.0	Panic disorder [episodic paroxysmal anxiety]
Neuropsychiatric	F41.1	Generalized anxiety disorder
Neuropsychiatric	F41.3	Other mixed anxiety disorders
Neuropsychiatric	F41.8	Other specified anxiety disorders
Neuropsychiatric	F43.11	Post-traumatic stress disorder, acute
Neuropsychiatric	F43.12	Post-traumatic stress disorder, chronic
Neuropsychiatric	F60.5	Obsessive-compulsive personality disorder
Neuropsychiatric	F90.0	Attention-deficit hyperactivity disorder, predominantly

		inattentive type
Neuropsychiatric	F90.1	Attention-deficit hyperactivity disorder, predominantly hyperactive type
Neuropsychiatric	F90.2	Attention-deficit hyperactivity disorder, combined type
Neuropsychiatric	F90.8	Attention-deficit hyperactivity disorder, other type

Coding Information

CPT/HCPCS Codes

Group 1 Paragraph:

CPT® code 81479 is used to describe multi-gene panels and single genes not otherwise classified.

Group 1 Codes: (32 Codes)

CODE	DESCRIPTION
81220	CFTR (CYSTIC FIBROSIS TRANSMEMBRANE CONDUCTANCE REGULATOR) (EG, CYSTIC FIBROSIS) GENE ANALYSIS; COMMON VARIANTS (EG, ACMG/ACOG GUIDELINES)
81225	CYP2C19 (CYTOCHROME P450, FAMILY 2, SUBFAMILY C, POLYPEPTIDE 19) (EG, DRUG METABOLISM), GENE ANALYSIS, COMMON VARIANTS (EG, *2, *3, *4, *8, *17)
81226	CYP2D6 (CYTOCHROME P450, FAMILY 2, SUBFAMILY D, POLYPEPTIDE 6) (EG, DRUG METABOLISM), GENE ANALYSIS, COMMON VARIANTS (EG, *2, *3, *4, *5, *6, *9, *10, *17, *19, *29, *35, *41, *1XN, *2XN, *4XN)
81227	CYP2C9 (CYTOCHROME P450, FAMILY 2, SUBFAMILY C, POLYPEPTIDE 9) (EG, DRUG METABOLISM), GENE ANALYSIS, COMMON VARIANTS (EG, *2, *3, *5, *6)
81231	CYP3A5 (CYTOCHROME P450 FAMILY 3 SUBFAMILY A MEMBER 5) (EG, DRUG METABOLISM), GENE ANALYSIS, COMMON VARIANTS (EG, *2, *3, *4, *5, *6, *7)
81232	DPYD (DIHYDROPYRIMIDINE DEHYDROGENASE) (EG, 5-FLUOROURACIL/5-FU AND CAPECITABINE DRUG METABOLISM), GENE ANALYSIS, COMMON VARIANT(S) (EG, *2A, *4, *5, *6)
81247	G6PD (GLUCOSE-6-PHOSPHATE DEHYDROGENASE) (EG, HEMOLYTIC ANEMIA,

CODE	DESCRIPTION
	JAUNDICE), GENE ANALYSIS; COMMON VARIANT(S) (EG, A, A-)
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)
81335	TPMT (THIOPURINE S-METHYLTRANSFERASE) (EG, DRUG METABOLISM), GENE ANALYSIS, COMMON VARIANTS (EG, *2, *3)
81350	UGT1A1 (UDP GLUCURONOSYLTRANSFERASE 1 FAMILY, POLYPEPTIDE A1) (EG, DRUG METABOLISM, HEREDITARY UNCONJUGATED HYPERBILIRUBINEMIA [GILBERT SYNDROME]) GENE ANALYSIS, COMMON VARIANTS (EG, *28, *36, *37)
81355	VKORC1 (VITAMIN K EPOXIDE REDUCTASE COMPLEX, SUBUNIT 1) (EG, WARFARIN METABOLISM), GENE ANALYSIS, COMMON VARIANT(S) (EG, -1639G>A, C.173+1000C>T)
81374	HLA CLASS I TYPING, LOW RESOLUTION (EG, ANTIGEN EQUIVALENTS); ONE ANTIGEN EQUIVALENT (EG, B*27), EACH
81377	HLA CLASS II TYPING, LOW RESOLUTION (EG, ANTIGEN EQUIVALENTS); ONE ANTIGEN EQUIVALENT, EACH
81381	HLA CLASS I TYPING, HIGH RESOLUTION (IE, ALLELES OR ALLELE GROUPS); ONE ALLELE OR ALLELE GROUP (EG, B*57:01P), EACH
81383	HLA CLASS II TYPING, HIGH RESOLUTION (IE, ALLELES OR ALLELE GROUPS); ONE ALLELE OR ALLELE GROUP (EG, HLA-DQB1*06:02P), EACH
81406	MOLECULAR PATHOLOGY PROCEDURE, LEVEL 7 (EG, ANALYSIS OF 11-25 EXONS BY DNA SEQUENCE ANALYSIS, MUTATION SCANNING OR DUPLICATION/DELETION VARIANTS OF 26-50 EXONS, CYTOGENOMIC ARRAY ANALYSIS FOR NEOPLASIA)
81418	DRUG METABOLISM (EG, PHARMACOGENOMICS) GENOMIC SEQUENCE ANALYSIS PANEL, MUST INCLUDE TESTING OF AT LEAST 6 GENES, INCLUDING CYP2C19, CYP2D6, AND CYP2D6 DUPLICATION/DELETION ANALYSIS
81479	UNLISTED MOLECULAR PATHOLOGY PROCEDURE
0029U	DRUG METABOLISM (ADVERSE DRUG REACTIONS AND DRUG RESPONSE), TARGETED SEQUENCE ANALYSIS (IE, CYP1A2, CYP2C19, CYP2C9, CYP2D6, CYP3A4, CYP3A5, CYP4F2, SLCO1B1, VKORC1 AND RS12777823)
0030U	DRUG METABOLISM (WARFARIN DRUG RESPONSE), TARGETED SEQUENCE ANALYSIS (IE, CYP2C9, CYP4F2, VKORC1, RS12777823)
0034U	TPMT (THIOPURINE S-METHYLTRANSFERASE), NUDT15 (NUDIX HYDROXYLASE 15)(EG, THIOPURINE METABOLISM), GENE ANALYSIS, COMMON VARIANTS (IE,

CODE	DESCRIPTION
	TPMT *2, *3A, *3B, *3C, *4, *5, *6, *8, *12; NUDT15 *3, *4, *5)
0070U	CYP2D6 (CYTOCHROME P450, FAMILY 2, SUBFAMILY D, POLYPEPTIDE 6) (EG, DRUG METABOLISM) GENE ANALYSIS, COMMON AND SELECT RARE VARIANTS (IE, *2, *3, *4, *4N, *5, *6, *7, *8, *9, *10, *11, *12, *13, *14A, *14B, *15, *17, *29, *35, *36, *41, *57, *61, *63, *68, *83, *XN)
0071U	CYP2D6 (CYTOCHROME P450, FAMILY 2, SUBFAMILY D, POLYPEPTIDE 6) (EG, DRUG METABOLISM) GENE ANALYSIS, FULL GENE SEQUENCE (LIST SEPARATELY IN ADDITION TO CODE FOR PRIMARY PROCEDURE)
0072U	CYP2D6 (CYTOCHROME P450, FAMILY 2, SUBFAMILY D, POLYPEPTIDE 6) (EG, DRUG METABOLISM) GENE ANALYSIS, TARGETED SEQUENCE ANALYSIS (IE, CYP2D6-2D7 HYBRID GENE) (LIST SEPARATELY IN ADDITION TO CODE FOR PRIMARY PROCEDURE)
0073U	CYP2D6 (CYTOCHROME P450, FAMILY 2, SUBFAMILY D, POLYPEPTIDE 6) (EG, DRUG METABOLISM) GENE ANALYSIS, TARGETED SEQUENCE ANALYSIS (IE, CYP2D7-2D6 HYBRID GENE) (LIST SEPARATELY IN ADDITION TO CODE FOR PRIMARY PROCEDURE)
0074U	CYP2D6 (CYTOCHROME P450, FAMILY 2, SUBFAMILY D, POLYPEPTIDE 6) (EG, DRUG METABOLISM) GENE ANALYSIS, TARGETED SEQUENCE ANALYSIS (IE, NON-DUPLICATED GENE WHEN DUPLICATION/MULTIPLICATION IS TRANS) (LIST SEPARATELY IN ADDITION TO CODE FOR PRIMARY PROCEDURE)
0075U	CYP2D6 (CYTOCHROME P450, FAMILY 2, SUBFAMILY D, POLYPEPTIDE 6) (EG, DRUG METABOLISM) GENE ANALYSIS, TARGETED SEQUENCE ANALYSIS (IE, 5' GENE DUPLICATION/MULTIPLICATION) (LIST SEPARATELY IN ADDITION TO CODE FOR PRIMARY PROCEDURE)
0076U	CYP2D6 (CYTOCHROME P450, FAMILY 2, SUBFAMILY D, POLYPEPTIDE 6) (EG, DRUG METABOLISM) GENE ANALYSIS, TARGETED SEQUENCE ANALYSIS (IE, 3' GENE DUPLICATION/ MULTIPLICATION) (LIST SEPARATELY IN ADDITION TO CODE FOR PRIMARY PROCEDURE)
0286U	CEP72 (CENTROSOMAL PROTEIN, 72-KDA), NUDT15 (NUDIX HYDROLASE 15) AND TPMT (THIOPURINE S-METHYLTRANSFERASE) (EG, DRUG METABOLISM) GENE ANALYSIS, COMMON VARIANTS
0345U	PSYCHIATRY (EG, DEPRESSION, ANXIETY, ATTENTION DEFICIT HYPERACTIVITY DISORDER [ADHD]), GENOMIC ANALYSIS PANEL, VARIANT ANALYSIS OF 15 GENES, INCLUDING DELETION/DUPLICATION ANALYSIS OF CYP2D6

CPT/HCPCS Modifiers

Group 1 Paragraph:

N/A

Group 1 Codes:

N/A

ICD-10-CM Codes that Support Medical Necessity

Group 1 Paragraph:

The following codes are for reference use only and are not to imply medical necessity or lack of medical necessity.

Group 1 Codes: (44 Codes)

CODE	DESCRIPTION
F20.0	Paranoid schizophrenia
F20.1	Disorganized schizophrenia
F20.2	Catatonic schizophrenia
F20.3	Undifferentiated schizophrenia
F20.5	Residual schizophrenia
F20.81	Schizophreniform disorder
F20.89	Other schizophrenia
F31.0	Bipolar disorder, current episode hypomanic
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
F31.31	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
F31.61	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
F31.71	Bipolar disorder, in partial remission, most recent episode hypomanic
F31.73	Bipolar disorder, in partial remission, most recent episode manic
F31.75	Bipolar disorder, in partial remission, most recent episode depressed
F31.77	Bipolar disorder, in partial remission, most recent episode mixed

CODE	DESCRIPTION
F32.1	Major depressive disorder, single episode, moderate
F32.2	Major depressive disorder, single episode, severe without psychotic features
F32.3	Major depressive disorder, single episode, severe with psychotic features
F32.4	Major depressive disorder, single episode, in partial remission
F33.1	Major depressive disorder, recurrent, moderate
F33.2	Major depressive disorder, recurrent severe without psychotic features
F33.3	Major depressive disorder, recurrent, severe with psychotic symptoms
F33.41	Major depressive disorder, recurrent, in partial remission
F40.11	Social phobia, generalized
F41.0	Panic disorder [episodic paroxysmal anxiety]
F41.1	Generalized anxiety disorder
F41.3	Other mixed anxiety disorders
F41.8	Other specified anxiety disorders
F43.11	Post-traumatic stress disorder, acute
F43.12	Post-traumatic stress disorder, chronic
F60.5	Obsessive-compulsive personality disorder
F90.0	Attention-deficit hyperactivity disorder, predominantly inattentive type
F90.1	Attention-deficit hyperactivity disorder, predominantly hyperactive type
F90.2	Attention-deficit hyperactivity disorder, combined type
F90.8	Attention-deficit hyperactivity disorder, other type

ICD-10-CM Codes that DO NOT Support Medical Necessity

Group 1 Paragraph:

N/A

Group 1 Codes:

N/A

ICD-10-PCS Codes

Group 1 Paragraph:

N/A

Group 1 Codes:

N/A

Additional ICD-10 Information

N/A

Bill Type Codes

Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the article does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the article should be assumed to apply equally to all claims.

N/A

Revenue Codes

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory. Unless specified in the article, services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the article should be assumed to apply equally to all Revenue Codes.

N/A

Other Coding Information

Group 1 Paragraph:

N/A

Group 1 Codes:

N/A

Revision History Information

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION
01/01/2023	R8	Under **CPT/HCPCS Codes Group 1: Codes** added 81418. This revision is due to the 2023 Annual/Q1 CPT/HCPCS Code Update and is effective on January 1, 2023.
12/07/2022	R7	Under **Article Text** revised Table 1 to add new row for HLA-A for tebentafusp. This

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION
		revision is effective for dates of service on or after 12/07/2022.
10/01/2022	R6	Under **CPT/HCPCS Codes Group 1: Codes** added 0345U. Typographical errors were corrected throughout the article. This revision is due to Q4 CPT®/HCPCS Code Update and is effective for dates of service on or after 10/1/2022.
06/16/2022	R5	Under Article Text, revised table 2 to add the last row. Formatting, punctuation and typographical errors were corrected throughout the Article. This revision is retroactive effective for dates of service on or after 4/29/2022.
04/28/2022	R4	Under **Article Text**, revised Table 2 to add the verbiage, "or Neuropsychiatric." This revision is effective on 4/28/2022
01/01/2022	R3	Under **Article Text** Table 1 Gene TPMT added 0034U and 0286U to the CPT Code column. Under **CPT/HCPCS Codes Group 1: Codes** added 0034U. This revision is retroactive effective for dates of service on or after 1/1/2022. Under **CPT/HCPCS Codes Group 1: Codes** added 0286U. This revision is due to the 2022 Annual CPT®/HCPCS Code Update and is effective 1/1/2022.
08/23/2021	R2	08/23/2021: A multigene panel must include all relevant genes and variants for its intended use to be reasonable and necessary. If, after the initial test is completed and additional testing is warranted and is reasonable and necessary as stated in the associated policy and as defined in the Repeat Germline Testing policy, an additional test may be subsequently performed." Under subheading Gene/CPT coding/Drug information revised the first sentence to read, "Table 1 represents relevant gene/drug associations from CPIC and FDA sources". Table 1 and Table 2 were deleted and a new Table 1 was added. Under subheading Covered multigene panels the verbiage, "with intended uses" was added to the subheading. Table 3 was renamed Table 2 and added the verbiage, "Table 2 represents covered multigene panels with specified uses that have successfully completed a TA. These tests must fulfill all the criteria above and may be further limited to specific indications listed by ICD-10 codes, when applicable". Rows 3 and 5 were added to the table. Under CPT/HCPCS Codes Group 1: Codes added 0029U. This revision is retroactive effective for dates of service on or after 8/23/2021. 01/01/2021: Under Article Text subheading Billing instructions: added registered mark

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION
		after CPT and added the verbiage, "If multiple drugs are being used/considered for the specified beneficiary on the claim, they should be added to the comment line separated by a "/" (example Drug 1/Drug 2). Do not list the same drug more than once". Under subheading Gene/CPT coding/Drug information revised the two tables to include CPT® code 81479 where N/A was previously listed. Under subheading Covered multigene panels revised table to update the intended use of each test. Under subheading ICD-10 codes associated with intended uses revised table to update intended use, added additional ICD-10 codes, and deleted unspecified codes. Under CPT/HCPCS Codes Group 1: Paragraph added the verbiage, "CPT® code 81479 is used to describe multi-gene panels and single genes not otherwise classified". Under CPT/HCPCS Codes Group 1: Codes added 81479. Under ICD-10 Codes that Support Medical Necessity Group 1: Codes added F20.0, F20.1, F20.2, F20.3, F20.5, F20.81, F20.89, F31.0, F31.11, F31.12, F31.13, F31.2, F31.31, F31.32, F31.4, F31.5, F31.61, F31.62, F31.63, F31.64, F31.71, F31.73, F31.75, F31.77, F40.11, F41.0, F41.1, F41.3, F41.8, F43.11, F43.12, F60.5, F90.0, F90.1, F90.2, F90.8 and deleted F32.9, F33.40, F33.9. This revision is retroactive effective for dates of service on or after 1/1/2021.
08/17/2020	R1	Under **Article Text** added the following verbiage that reads: "Relevant National Coverage Determinations (NCDs): • NCD 90:1: Testing for CYP2C9 and VKORC1 for Warfarin dosage must adhere to the requirements set forth in this NCD." Discrepancies within the tables have been corrected and a column has been added listing brand name medications in tables 1 and 2. The link below table 2 has been revised. Under **CPT/HCPCS Codes – Group 1: Codes** added codes 81247, 81328, 81374, 81377, 81381, 81383, and deleted codes 81371, 81373 and 81379.

Associated Documents

Related Local Coverage Documents

LCDs

L38337 - MolDX: Pharmacogenomics Testing

Related National Coverage Documents

N/A

Statutory Requirements URLs

N/A

Rules and Regulations URLs

N/A

CMS Manual Explanations URLs

N/A

Other URLs

N/A

Public Versions

UPDATED ON	EFFECTIVE DATES	STATUS
01/06/2023	01/01/2023 - N/A	Currently in Effect (This Version)
12/23/2022	12/07/2022 - 12/31/2022	Superseded
11/02/2022	10/01/2022 - 12/06/2022	Superseded
06/16/2022	06/16/2022 - 09/30/2022	Superseded
05/20/2022	04/28/2022 - 06/15/2022	Superseded
02/07/2022	01/01/2022 - 04/27/2022	Superseded
Some older versions have been archived. Please visit the MCD Archive Site to retrieve them.		

Keywords

N/A