Geisinger

Geisinger Health Plan Policies and Procedure Manual

Policy: MP239

Section: Medical Benefit Policy

Subject: Pharmacogenetic Testing

I. Policy: Pharmacogenetic Testing

II. Purpose/Objective:

To provide a policy of coverage regarding Pharmacogenetic Testing

III. Responsibility:

A. Medical Directors

B. Medical Management Department

IV. Required Definitions

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards of good medical treatment practiced by the general medical community;
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

Medicaid Business Segment

Medical Necessity shall mean a service or benefit that is compensable under the Medical Assistance Program and if it meets any one of the following standards:

(i) the service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.
(ii) the service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or development effects of an illness, condition, injury or disability.
(iii) the service or benefit will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for members of the same age.

INDICATIONS:
Pharmacogenetic testing is considered to be medically necessary when the identification of a specific gene marker is noted to be clinically necessary before initiation of therapy by the U.S. Food and Drug Administration as noted in the Indications section of the prescribing information and/or supported by NCCN Guidelines. Examples include, but are not limited to any of the following:

- ABCG2 for rosuvastatin (Crestor)
- ALK for crizotinib (Xalkori) or ceritinib (Zykadia)
- ALK for crizotinib (Xalkori), alectinib (Alecensa) or ceritinib (Zykadia) for the treatment of non-small cell lung cancer (NSCLC).
- BCR/ABL1 for dasatnib, imatinib, nilotinib, ponatinib and/or bosutinib
- BRAF and NRAS for cetuximab (Erbitux) or panitumumab (Vectibix).
- BRAF for vemurafenib (Zelboraf), dabrafenib (Tafinlar), pembrolizumab (Keytruda) or encorafenib (Braftovi)
- BRCA for olaparib (Lynparza), rucaparib (Rubraca)
- CACNA1S for volatile anesthetics
- CTFR for ivacaftor (Kalydeco) or lumacaftor/ivacaftor (Orkambi)
- CYP2B6 for efanvirenz (Sustiva)
- CYP2C19 for clopidogrel (Plavix) {**May be considered for program exception for the Medicaid business segment for this indication** Antidepressants, Barbiturates, Proton pump inhibitors, Mephenytoin
- CYP2C9 for warfarin metabolism, Celebrex, Marinol, Balversa, Ansaid, Cerebyx, Mobic, Dilantin, Feldene, Mayzent
- CYP2D6 for tetrabenazine (Xenazine) greater than 50 mg per day, eliglustat (Cerdelga), deutetrabenazine (austedo) greater than 36mg/day, Antidepressants for treatment of depression (including SSRI's) , Anti-psychotics for treatment of schizophrenia, atomoxetine, codeine, ondansetron, tropisetron, tamoxifen, tramadol, hydrocodone
- CYP3A5 for tacrolimus (Prograf, Protopic)
- CYP4F2 for warfarin
- DYPD gene mutation for capecitabine or 5-fluorouracil
- EGFR for cetuximab (Erbitux), erlotinib (Tarceva) osimertinib (Tagrisso) and/or afatinib dimaleate (Gilotrif)
- ER for fulvestarnt (Faslodex)
- F2
- F5
- FGFR2 for pegaptanib (Pemazyre)
- FGFR3 for erdafitinib (Balversa)
- FTL3 mutation assay for midostaurin (Rydapt), gilternib (Xospata) or sorafenib (Nexavar).
- G6PD for rasburicase (Elitek)
- GBA for velaglucerase alfa
- Genotype 1 chronic hepatits C for teleprevir (Incivik)
- HER2/neu for traztuzumab (Herceptin) and/or lapitinib (Tykerb)
- HLA-A for carbamazepine (Tegretol)
- HLA-B*1502 for persons of Asian ancestry prior to carbamazepine (Tegretol)
- HLA-B*5701 for Abacavir (Ziagen)
- HLA-B*5801 for allopurinol
- IFNL3, IFNL4 for peginterferon (Pegasys, Pegintron, Sylatron)
- K-RAS for cetuximab (Erbitux) and/or panitumumab (vectibix)
- KIT
- MGMT gene methylation assay for temozolomide (Temodar)
- MT-RNR1 for aminoglycosides
- NS3 Q80K for simeprevir (Olysio)
- NUDT15 for thiopurines
- PDGFRß for treatment with imatinib mesylate (Gleevec).
- PDL1 for pembrolizumab (Keytruda), durvalumab (Imfinzi).
- PD-L1 for treatment with durvalumab (Imfinzi); atezolizumab (Tecentriq), pembrolilzumab (Keytruda).
- PIK3CA for alpelisib (Piqray)
- ROS1
- RYR1 for inhaled anesthetics

- SLCO1B1 for Statins (class): simvastatin, pravastatin, atorvastatin, lovastatin, rosuvastatin, fluvastatin, pitavastatin
- TPMT gene mutation or phenotypic assay for 6-mercaptopurine or azathioprine therapy (See MP311 for additional information)
- UGT1A1 for irinotecan treatment
- VKORC1 for warfarin metabolism

Generally, pharmacogenetic testing such as mutation analysis or genotyping is considered to be medical necessary when:

- The member is a candidate for a targeted therapy as noted above; and
- The testing methodology used to investigate and identify the genetic mutation or biomarker has been proven to be clinically valid and analytically valid; and
- The test result has been proven to have clinical utility and will have a direct impact on the decision making and/or the member's clinical outcome; or
- When medications are being considered for use or are being administered that are known to have a gene-drug interaction that has been demonstrated to be clinically actionable as defined by the FDA.

If a single gene or allele test is ordered, but the laboratory tests that single gene or allele on a platform that looks for variants in other genes/alleles as well, the test is considered a single gene/allele test for coverage purposes and only the single gene test will be considered medically necessary.

A multi-gene panel is considered medically necessary if more than one single gene on that panel would be considered medically necessary for safe use of the medication in question or if multiple drugs are being considered (each fulfilling the criteria of actionable gene-drug interactions identified above) that have different relevant genes. A multi-gene panel is considered unproven and not medically necessary, therefore **NOT COVERED** if only a single gene on the panel is considered reasonable and necessary.

MEDICARE BUSINESS SEGMENT:

Pharmacogenomic testing for warfarin metabolism is eligible for coverage once per patient lifetime, corresponding to CYP2C9 and VKORC1 genotypes, respectively. Alleles CYP2C9 and VKORC1 for warfarin dosing are coverable per NCD 90.1 via coverage with evidence development. (http://www.cms.gov/medicare-coverage-database/details/ncddetails.aspx?NCDId=333&ncdver=1&bc=BAAAgAAAAAAA&)

Pharmacogenomic testing of CYP2C19 for clopidogrel metabolism is eligible for coverage in individuals with acute coronary syndrome undergoing a percutaneous coronary intervention who are initiating or re-initiating clopidigrel therapy.

Pharmacogenomic testing of CYP2D6 is eligible for coverage in individuals in whom:

- Amitriptyline or nortriptyline is initiated for depressive disorder; or
- Tetrabenazine dosing greater than 50 mg/day
- Antidepressants for treatment of depression (including SSRI's) , Anti-psychotics for treatment of schizophrenia, atomoxetine, codeine, ondansetron, tropisetron, tamoxifen, tramadol, hydrocodone

MEDICAID BUSINESS SEGMENT:

Pharmacogenomic testing of CYP2C19 for clopidogrel metabolism is eligible for coverage as an Option 2 program exception once per patient lifetime when the request for this test is for an insured individual with documented moderate to high risk for an acute coronary event.

EXCLUSIONS:

Unless otherwise mandated, the Plan does **NOT** provide coverage for the use of the following pharmacogenetic testing because they are considered experimental, investigational or unproven. The Geisinger Technology Assessment Committee evaluated this technology and concluded that there is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of this test on health outcomes when compared to established tests or technologies.

- CYP2D6 gene mutation for any of the following
  - Opioid analgesics
  - Tamoxifen resistance
- CYP1A2
- CYP3A4
- OPRM1 (μ-opioid receptor)
- OPRK1 (k-opioid receptor)

- DRD1 (dopamine receptor)
- DRD2 (dopamine receptor)
- DRD4 (dopamine receptor)
- DAT1 or SLC6A3 (dopamine transporter)
- DBH (dopamine beta-hydroxylase)
- TYMS (thymidylate synthetase) (eg, 5-fluorouracil/5-FU drug metabolism)
- IFNL3 (prediction of virological response to pegylated-interferon-alpha and ribavirin combination therapy)
- MTHFR (5, 10-methylenetetrahydrofolate reductase) (eg, hereditary hypercoagulability) gene analysis
- HTR2A (eg, citalopram metabolism) gene analysis, common variants
- HTR2C (eg, citalopram metabolism) gene analysis, common variants
- UGT2B15 (uridine diphosphate glycosyltransferase 2 family, member 15)
- COMT (catechol-O-methyl-transferase)

Unless otherwise mandated, the Plan does NOT provide coverage for the use of any of the following pharmacogenetic testing panels because they are considered to be of unproven clinical value and not medically necessary:

- AIBioTech CardioloGene Genetic Panel
- AIBioTech Pain Management Panel
- AIBioTech PsychiaGene Genetic Panel
- AIBioTech Urologene Panel
- GeneSight ADHD **(exclusion not applicable to Medicare/Medicaid per MolDx L38294)**
- GeneSight Assay for Refractory Depression **(exclusion not applicable to Medicare/Medicaid per MolDx L38294**
- GeneSight Psychotropic **(exclusion not applicable to Medicare/Medicaid per MolDx L38294) (may be considered for Medicaid via Program Exception)**
- GeneSight Analgesic **(exclusion not applicable to Medicare/Medicaid per MolDx L38294)**
- Genecept Assay **(exclusion not applicable to Medicare/Medicaid per MolDx L38294)**

- Genomind PGx **(may be considered for Medicaid via Program Exception)**
- SureGene Test for Antipsychotic and Antidepressant Response
- Millenium Pharmacogenetic Testing
- Proove Drug Metabolism Panel
- Proove Narcotic Risk Assay
- YouScript Panel
- PharmaRisk Basic
- PharmaRisk Psychiatric Panel
- Molecular Testing Labs Psychotropic Medication Panel
- Physicians Choice Laboratory Services Pharmacogenetic Testing
- NeuroIDGenetics **(exclusion not applicable to Medicare/Medicaid per MolDx L38294)**

- CardioIDGenetics
- OnDose testing to allow area under the curve (AUC)-targeted 5-fluorouracil dosing
- OneOme RightMed Pharmacogenomic Test
- PGx Express CORE Anxiety & Depression (Genomind) **(may be considered for Medicaid via Program Exception)**
- Tempus nP
- IDgenetix **(may be considered for Medicaid via Program Exception)**

Note: A complete description of the process by which a given technology or service is evaluated and determined to be experimental, investigational or unproven services is outlined in **MP 15 - Experimental Investigational or Unproven Services or Treatment.**

Medicaid Business Segment:

Any requests for services, that do not meet criteria set in the PARP, will be evaluated on a case by case basis.

CODING ASSOCIATED WITH: Pharmacogenetic Testing

The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws

regarding coverage of specific services. Please note that per Medicare coverage rules, only specific CPT/HCPCS Codes may be covered for the Medicare Business Segment. Please consult the CMS website at www.cms.gov ***or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements.***

0028U CYP2D6 (cytochrome P450, family 2, subfamily D, polypeptide 6) (eg, drug metabolism) gene analysis, copy number variants, common variants with reflex to targeted sequence analysis
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)
0031U CYP1A2 (cytochrome P450 family 1, subfamily A, member 2) (eg, drug metabolism) gene analysis, common variants (ie, *1F, *1K, *6, *7)
0032U COMT (catechol-O-methyltransferase) (drug metabolism) gene analysis, c.472G>A (rs4680) variant
0033U Htr2a htr2c genes
0034U TPMT (thiopurine S-methyltransferase), NUDT15 (nudix hydroxylase 15) (eg, thiopurine metabolism), gene analysis, common variants (ie, 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-hyphen2D7 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-hyphen2D6 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-hyphenduplicated 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)
0078U Pain management (opioid-use disorder) genotyping panel, 16 common variants (ie, ABCB1, COMT, DAT1, DBH, DOR, DRD1, DRD2, DRD4, GABA, GAL, HTR2A, HTTLPR, MTHFR, MUOR, OPRK1, OPRM1), buccal swab or other germline tissue sample, algorithm reported as positive or negative risk of opioid-use disorder
0154U Oncology (urothelial cancer), RNA, analysis by real-time RT-PCR of the FGFR3 (fibroblast growth factor receptor 3) gene analysis (ie, p.R248C [c.742C>T], p.S249C [c.746C>G], p.G370C [c.1108G>T], p.Y373C [c.1118A>G], FGFR3-TACC3v1, and FGFR3-TACC3v3) utilizing formalin-fixed paraffin-embedded urothelial cancer tumor tissue, reported as FGFR gene alteration status
0155U (phosphatidylinositol-4, 5-biphosphate 3-kinase, catalytic subunit alpha) (e.g., colorectal and breast cancer) gene analysis,
0169U NUDT15 (nudix hydrolase 15) and TPMT (thiopurine S-methyltransferase) (eg, drug metabolism) gene analysis, common variants
0173U Psychiatry (i.e., depression, anxiety), genomic analysis panel, includes variant analysis of 14 genes
0174U Oncology (solid tumor), mass spectrometric 30 protein targets, formalin-fixed paraffin-embedded tissue, prognostic and predictive algorithm reported as likely, unlikely, or uncertain benefit of 39 chemotherapy and targeted therapeutic oncology agent
0175U Psychiatry (e.g., depression, anxiety), genomic analysis panel, variant analysis of 15 genes *{PGx Express CORE Anxiety & Depression (Genomind)}*
0177U Oncology (breast cancer), DNA, PIK3CA (phosphatidylinositol-4,5-bisphosphate 3-kinase catalytic subunit alpha) gene analysis of 11 gene variants utilizing plasma, reported as PIK3CA gene mutation status
0193U ABCGR gene
0380U Drug metabolism (adverse drug reactions and drug response), targeted sequence analysis, 20 gene variants and CYP2D6 deletion or duplication analysis with reported genotype and phenotype
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 *{GeneSight Psychotropic}*
0392U Drug metabolism (depression, anxiety, attention deficit hyperactivity disorder [ADHD]), gene-drug interactions, variant analysis of 16 genes, including deletion/duplication analysis of CYP2D6, reported as impact of gene-drug interaction for each drug
0411U Psychiatry (eg, depression, anxiety, attention deficit hyperactivity disorder [ADHD]), genomic analysis panel, variant analysis of 15 genes, including deletion/duplication analysis of CYP2D6 *{IDgenetix}*
0419U Neuropsychiatry (eg, depression, anxiety), genomic sequence analysis panel, variant analysis of 13 genes, saliva or buccal swab, report of each gene phenotype *{Tempus nP}*
0423U Psychiatry (eg, depression, anxiety), genomic analysis panel, including variant analysis of 26 genes, buccal swab, report including metabolizer status and risk of drug toxicity by condition *{Genomind PDx}*
0434U Drug metabolism (adverse drug reactions and drug response), genomic analysis panel, variant analysis of 25 genes with reported phenotypes
0438U Drug metabolism (adverse drug reactions and drug response), buccal specimen, gene-drug interactions, variant analysis of 33 genes, including deletion/duplication analysis of CYP2D6, including reported phenotypes and impacted gene-drug interactions
0461U Oncology, pharmacogenomic analysis of single-nucleotide polymorphism (SNP) genotyping by real-time PCR of 24 genes, whole blood or buccal swab, with variant analysis, including impacted gene-drug interactions and reported phenotypes (RightMed® Oncology Medication Report)
81210 BRAF (v-raf murine sarcoma viral oncogene homolog B1) (eg, colon cancer), gene analysis, V600E variant
81210 BRAF (v-raf murine sarcoma viral oncogene homolog B1) (eg, colon cancer), gene analysis, V600E variant
81220 CFTR (cystic fibrosis transmembrane conductance regulator) (eg, cystic fibrosis) gene analysis; common variants (eg, ACMG/ACOG guidelines)
81221 (cystic fibrosis transmembrane conductance regulator) (eg, cystic fibrosis) gene analysis; known familial variants
81222 (cystic fibrosis transmembrane conductance regulator) (eg, cystic fibrosis) gene analysis; duplication/deletion variants
81225 CYP2C19 gene analysis, common variants
81226 CYP2D6 (cytochrome P450, family 2, subfamily D, polypeptide 6) (eg, drug metabolism), gene analysis, common variants
81227 CYP2C9 gene analysis, common variants
81230 CYP3A4 gene analysis
81231 CYP3A5 gene analysis
81232 DPYD dihydropyrimidine dehydrogenase gene analysis
81235 EGFR (epidermal growth factor receptor) (eg, non-small cell lung cancer) gene analysis, common variants (eg, exon 19 LREA deletion, L858R, T790M, G719A, G719S, L861Q)
81240 F2 (prothrombin, coagulation factor II) (eg, hereditary hypercoagulability) gene analysis, 20210G>A variant
81241 F5 (coagulation factor V) (eg, hereditary hpercoagulability) gene analysis, leiden variant
81245 FLT3 (fms-related tyrosine kinase 3) (eg, acute myeloid leukemia), gene analysis; internal tandem duplication (ITD) variants (ie, exons 14, 15)
81246 FLT3 (fms-related tyrosine kinase 3) (eg, acute myeloid leukemia), gene analysis; tyrosine kinase domain (TKD) variants (eg, D835, I836)
81247 G6PD
81275 KRAS (v-Ki-ras2 Kirsten rat sarcoma viral oncogene) (eg, carcinoma) gene analysis, variants in codons 12 and 13
81276 KRAS (kristen rat sarcome viral oncogene homolog) (eg, carcinoma) gene analysis; additional variant(s) (eg, codon 61, codon 146)
81283 IFNL3 interferon lambda, gene analysis
81287 MGMT (O-6-methylguanine-DNA methyltransferase) (eg, glioblastoma multiforme), methylation analysis
81288 MLH1 (mutL homolog 1, colon cancer, nonpolyposis type 2) (eg, hereditary non-polyposis colorectal cancer, lynch syndrome) gene analysis; promoter methylation analysis
81291 MTHFR (5, 10-methylenetetrahydrofolate reductase) (eg, hereditary hypercoagulability) gene analysis, common variants (eg, 677T, 1298C)
81309 PIK3CA (PHOSPHATIDYLINOSITOL-4, 5-BIPHOSPHATE 3-KINASE, CATALYTIC SUBUNIT ALPHA) (EG, COLORECTAL AND BREAST CANCER) gene analysis, targeted sequence analysis (exons 7,9,20)
81328 SLCO1B1 solute carrier organic anion transporter family, member 1B1
81335 TPMT (thiopurine S-methyltransferase, gene analysis, common variants
81346 TYMS (thymidylate synthease, gene analysis (eg, 5-FU drug metabolism)
81350 UGT1A1 (UDP glucuronosyltransferase 1 family, polypeptide A1) (eg, irinotecan metabolism), gene analysis, common variants
81355 VKORC1 gene analysis, common variants
81371 HLA class I and II typing, low resolution (eg, antigen equivalents); HLA-A, -B, and -DRB1 (eg, verification typing)
81376 HLA class II typing, low resolution (eg, antigen equivalents); one locus (eg, HLA-DRB1, -DRB3/4/5, -DQB1, -DQA1, -DPB1, or -DPA1), each

81381 HLA Class I typing, high resolution (ie, alleles or allele groups); 1 allele or allele group (eg, B*57:01P), each
81381 HLA class I typing, high resolution (ie, alleles or allele groups); one allele or allele group (eg, B*57: O1P), each
81400-81408
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 5HTT
81479 CYP1A2
81479 Mu 1 Opioid Receptor genotyping
81479 NAT 2
81479 Serotonin Transporter genotyping
81479 GeneSight Psychotropic Assay
82172 apolipoprotein, each
82542 Column chromatography, includes mass spectrometry, if performed
82657 Enzyme activity in blood cells, cultured cells or tissue, not elsewhere specified, nonradioactive substrate, each
82777 galectin-3
84431 Thromboxane metabolite(s), including thromboxane if performed, urine
84433 Thiopurine S-methyltransferase (TPMT)
86352 cellular function assay involving stimulation (eg, mitogen or antigen) and detection of biomarker (eg, ATP)
G9143 Warfarin responsiveness testing by genetic technique using any method, any number of specimen(s)

LINE OF BUSINESS:
Eligibility and contract specific benefits, limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD's and NCD's will supercede this policy. For PA Medicaid Business segment, this policy applies as written.

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Practice Center under contract No. 290-02-0022). Rockville (MD): Agency for Healthcare Research and Quality (AHRQ); 2008 Nov 12. 193 p. Also available: http://www.cms.hhs.gov/determinationprocess/downloads/id61TA.pdf.

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Hayes Inc. GTE database STA2R SureGene Test for Antipsychotic and Antidepressant Response for Pharmacogenetic Testing (SureGene LLC) Jan 2014

Hayes Inc. GTE database Cytochrome P450 3A4 (CYP3A4) for Drug Metabolism. Oct. 2012

Hayes Inc. GTE database Cytochrome P450 3A5 (CYP3A5) Testing for Predict Response to Tacrolimus No, 2013

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This policy will be revised as necessary and reviewed no less than annually.

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Revised: 8/13 (added coverage for Medicare business segment), 9/14 (expanded policy scope), 4/15 (added panels to exclusions); 7/15 (added Medicare coverage); 8/17 (add indications and exclusions); 8/18 (add indications and exclusions); 8/19 (add indications and exclusions), 8/20 (add indications and exclusions); 7/21(add indications); 3/22 (Add indications and exclusions); 3/23 (add coverage indications); 3/24 (revise Indications and Exclusions)

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