

<b>CMS Manual System</b>	<b>Department of Health &amp; Human Services (DHHS)</b>
<b>Pub 100-04 Medicare Claims Processing</b>	<b>Centers for Medicare &amp; Medicaid Services (CMS)</b>
<b>Transmittal 2639</b>	<b>Date: January 25, 2013</b>
	<b>Change Request 8162</b>

**SUBJECT: Healthcare Common Procedure Coding System (HCPCS) Codes Subject to and Excluded from Clinical Laboratory Improvement Amendments (CLIA) Edits**

**I. SUMMARY OF CHANGES:** This change request informs contractors about the new HCPCS codes for 2013 that are both subject to and excluded from CLIA edits. This Recurring Update applies to Chapter 16, Section 70-9.

**EFFECTIVE DATE: January 1, 2013**

**IMPLEMENTATION DATE: April 1, 2013**

*Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.*

**II. CHANGES IN MANUAL INSTRUCTIONS:** (N/A if manual is not updated)

R=REVISED, N=NEW, D=DELETED-Only One Per Row.

<b>R/N/D</b>	<b>CHAPTER / SECTION / SUBSECTION / TITLE</b>
N/A	

**III. FUNDING:**

**For Fiscal Intermediaries (FIs), Regional Home Health Intermediaries (RHHIs) and/or Carriers:**

No additional funding will be provided by CMS; Contractors activities are to be carried out with their operating budgets.

**For Medicare Administrative Contractors (MACs):**

The Medicare Administrative contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC statement of Work. The contractor is not obliged to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

**IV. ATTACHMENTS:**

**Recurring Update Notification**

*\*Unless otherwise specified, the effective date is the date of service.*

# Attachment - Recurring Update Notification

Pub. 100-04	Transmittal: 2639	Date: January 25, 2013	Change Request: 8162
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**SUBJECT: Healthcare Common Procedure Coding System (HCPCS) Codes Subject to and Excluded from Clinical Laboratory Improvement Amendments (CLIA) Edits**

**EFFECTIVE DATE: January 1, 2013**

**IMPLEMENTATION DATE: April 1, 2013**

## I. GENERAL INFORMATION

**A. Background:** The Clinical Laboratory Improvement Amendments (CLIA) regulations require a facility to be appropriately certified for each test performed. To ensure that Medicare & Medicaid only pay for laboratory tests performed in certified facilities, each claim for a HCPCS code that is considered a CLIA laboratory test is currently edited at the CLIA certificate level.

The HCPCS codes that are considered a laboratory test under CLIA change each year. Contractors need to be informed about the new HCPCS codes that are both subject to CLIA edits and excluded from CLIA edits.

The following HCPCS codes were discontinued on December 31, 2012:

- 83890 - Molecular diagnostics; molecular isolation or extraction, each nucleic acid type (i.e., DNA or RNA)
- 83891 - Molecular diagnostics; isolation or extraction of highly purified nucleic acid, each nucleic acid type (i.e., DNA or RNA),
- 83892 - Molecular diagnostics; enzymatic digestion, each enzyme treatment,
- 83893 - Molecular diagnostics; dot/slot blot production, each nucleic acid preparation,
- 83894 - Molecular diagnostics; separation by gel electrophoresis (e.g., agarose, polyacrylamide), each nucleic acid preparation,
- 83896 - Molecular diagnostics; nucleic acid probe, each;
- 83897 - Molecular diagnostics; nucleic acid transfer (e.g., southern, northern), each nucleic acid preparation,
- 83898 - Molecular diagnostics; amplification, target, each nucleic acid sequence,
- 83900 - Molecular Diagnostics; Amplification, Target, Multiplex, First 2 Nucleic Acid Sequences,
- 83901 - Molecular diagnostics; amplification, target, multiplex, each additional nucleic acid sequence beyond 2 (list separately in addition to code for primary procedure),
- 83902 - Molecular diagnostics; reverse transcription,
- 83903 - Molecular diagnostics; mutation scanning, by physical properties (e.g., single strand conformational polymorphisms [sscp], heteroduplex, denaturing gradient gel electrophoresis [DGGE], RNA'ASE a), single segment, each,
- 83904 - Molecular diagnostics; mutation identification by sequencing, single segment, each segment,
- 83905 - Molecular diagnostics; mutation identification by allele specific transcription, single segment, each segment,
- 83906 - Molecular diagnostics; mutation identification by allele specific translation, single segment, each segment,
- 83907 - Molecular diagnostics; lysis of cells prior to nucleic acid extraction (e.g., stool specimens, paraffin embedded tissue), each specimen
- 83908 - Molecular diagnostics; amplification, signal, each nucleic acid sequence,
- 83909 - Molecular diagnostics; separation and identification by high resolution technique (e.g., capillary electrophoresis), each nucleic acid preparation,
- 83912 - Molecular diagnostics; interpretation and report,
- 83913 - Molecular diagnostics; RNA stabilization,

- 83914 - Mutation identification by enzymatic ligation or primer extension, single segment, each segment (e.g., oligonucleotide ligation assay [OLA], single base chain extension [SBCE], or allele-specific primer extension [ASPE]),
- 88384 - Array-based evaluation of multiple molecular probes; 11 through 50 probes,
- 88385 - Array-based evaluation of multiple molecular probes; 51 through 250 probes,
- 88386 - Array-based evaluation of multiple molecular probes; 251 through 500 probes,
- 0030T - Antiprothrombin (phospholipid cofactor) antibody, each IG class,
- 0279T - Cell enumeration using immunologic selection and identification in fluid specimen (e.g., circulating tumor cells in blood), and
- 0280T - Cell enumeration using immunologic selection and identification in fluid specimen (e.g., circulating tumor cells in blood); interpretation and report.

In 2012, there were 101 new HCPCS codes for molecular pathology (i.e., 81200 through 81408) that were subject to the CLIA regulations, were not payable by Medicare and were not included in the recurring update notification for 2012 (i.e., Change Request 7778). For 2013, these 101 molecular HCPCS codes have been placed on the Medicare Clinical Laboratory Fee Schedule. The 101 molecular HCPCS codes are included in the attachment.

The HCPCS codes listed below are new for 2013 and are subject to CLIA edits. The list does not include new HCPCS codes for waived tests or provider-performed procedures. The HCPCS codes listed below require a facility to have either a CLIA certificate of registration (certificate type code 9), a CLIA certificate of compliance (certificate type code 1), or a CLIA certificate of accreditation (certificate type code 3). A facility without a valid, current, CLIA certificate, with a current CLIA certificate of waiver (certificate type code 2) or with a current CLIA certificate for provider-performed microscopy procedures (certificate type code 4) must not be permitted to be paid for these tests. The new HCPCS codes for 2013 are the following:

- 81201 - APC (adenomatous polyposis coli) (e.g., familial adenomatosis polyposis [FAP], attenuated FAP) gene analysis; full gene sequence,
- 81202 - APC (adenomatous polyposis coli) (e.g., familial adenomatosis polyposis [FAP], attenuated FAP) gene analysis; known familial variants,
- 81203 - APC (adenomatous polyposis coli) (e.g., familial adenomatosis polyposis [FAP], attenuated FAP) gene analysis; duplication/deletion variants,
- 81235 - EGFR (epidermal growth factor receptor) (e.g., non-small cell lung cancer) gene analysis, common variants (e.g., exon 19 lrea deletion, L858R, T790M, G719A, G719S, L861Q),
- 81252 - GJB2 (gap junction protein, beta 2, 26kDa; Connexin 26) (e.g., nonsyndromic hearing loss) gene analysis; full gene sequence,
- 81253 - GJB2 (gap junction protein, beta 2, 26kDa; known familial variants,
- 81254 - GJB6 (gap junction protein, beta 6, 30 kDa, Connexin 30) (e.g., nonsyndromic hearing loss) gene analysis, common variants (eg, 309KB [DEL(GJB6-D13S1830)] and 232KB [DEL(GJB6-D13S1854)]),
- 81321 - PTEN (phosphatase and tensin homolog) (e.g., Cowden syndrome, PTEN hamartoma tumor syndrome) gene analysis; full sequence analysis,
- 81322 - PTEN (phosphatase and tensin homolog) (e.g., Cowden syndrome, PTEN hamartoma tumor syndrome) gene analysis; known familial variant,
- 81323 - PTEN (phosphatase and tensin homolog) (e.g., Cowden syndrome, PTEN hamartoma tumor syndrome) gene analysis; duplication/deletion variant,
- 81324 - PMP22 (peripheral myelin protein 22) (e.g., Charcot-Marie-Tooth, hereditary neuropathy with liability to pressure palsies) gene analysis; duplication/deletion analysis,
- 81325 - PMP22 (peripheral myelin protein 22) (e.g., Charcot-Marie-Tooth, hereditary neuropathy with liability to pressure palsies) gene analysis; full sequence analysis,
- 81326 - PMP22 (peripheral myelin protein 22) (e.g., Charcot-Marie-Tooth, hereditary neuropathy with liability to pressure palsies) gene analysis; known familial variant,
- 81479 - Unlisted molecular pathology procedure,
- 82777 - Galectin-3,

- 86152 - Cell enumeration using immunologic selection and identification in fluid specimen (e.g., circulating tumor cells in blood),
- 86153 - Cell enumeration using immunologic selection and identification in fluid specimen (e.g., circulating tumor cells in blood); physician interpretation and report, when required,
- 86711 - JC (John Cunningham) virus,
- 86828 - Antibody to human leukocyte antigens (HLA), solid phase assays (e.g., microspheres or beads; ELISA, flow cytometry); qualitative assessment of the presence or absence of antibody(ies) to HLA Class I and Class II HLA antigens,
- 86829 - Antibody to human leukocyte antigens (HLA), solid phase assays (e.g., microspheres or beads, ELISA, flow cytometry); qualitative assessment of the presence or absence of antibody(ies) to HLA Class I or Class II HLA antigens,
- 86830 - Antibody to human leukocyte antigens (HLA), solid phase assays (e.g., microspheres or beads, ELISA, flow cytometry); antibody identification by qualitative panel using complete HLA phenotypes, HLA Class I,
- 86831 - Antibody to human leukocyte antigens (HLA), solid phase assays (e.g., microspheres or beads, ELISA, flow cytometry); antibody identification by qualitative panel using complete HLA phenotypes, HLA Class II,
- 86832 - Antibody to human leukocyte antigens (HLA), solid phase assays (e.g., microspheres or beads, ELISA, flow cytometry); high definition qualitative panel for identification of antibody specificities (e.g., individual antigen per bead methodology), HLA Class I,
- 86833 - Antibody to human leukocyte antigens (HLA), solid phase assays (e.g., microspheres or beads, ELISA, flow cytometry); high definition qualitative panel for identification of antibody specificities (e.g., individual antigen per bead methodology), HLA Class II,
- 86834 - Antibody to human leukocyte antigens (HLA), solid phase assays (e.g., microspheres or beads, ELISA, flow cytometry); semi-quantitative panel (e.g., titer), HLA Class I,
- 86835 - Antibody to human leukocyte antigens (HLA), solid phase assays (e.g., microspheres or beads, ELISA, flow cytometry); semi-quantitative panel (e.g., titer), HLA Class II,
- 87631 - Infectious agent detection by nucleic acid (DNA or RNA); respiratory virus (e.g., adenovirus, influenza virus, coronavirus, metapneumovirus, parainfluenza virus, respiratory syncytial virus, rhinovirus), multiplex reverse transcription and amplified probe technique, multiple types or subtypes, 3-5 targets,
- 87632 - Infectious agent detection by nucleic acid (DNA or RNA); respiratory virus (e.g., adenovirus, influenza virus, coronavirus, metapneumovirus, parainfluenza virus, respiratory syncytial virus, rhinovirus), multiplex reverse transcription and amplified probe technique, multiple types or subtypes, 6-11 targets,
- 87633 - Infectious agent detection by nucleic acid (DNA or RNA); respiratory virus (e.g., adenovirus, influenza virus, coronavirus, metapneumovirus, parainfluenza virus, respiratory syncytial virus, rhinovirus), multiplex reverse transcription and amplified probe technique, multiple types or subtypes, 12-25 targets,
- 87910 - Infectious agent genotype analysis by nucleic acid (DNA or RNA); cytomegalovirus,
- 87912 - Infectious agent genotype analysis by nucleic acid (DNA or RNA); Hepatitis B virus, and
- 88375 - Optical endoscopic image(s), interpretation and report, real-time or referred, each endoscopic session.

Additionally, there were 9 new HCPCS codes for multi-analyte assays with algorithmic analyses (i.e., 81500 through 81512, and 81599) in 2013. The testing described by these codes is subject to the CLIA regulations, however, they are not payable by Medicare for CY 2013. Hence, these 9 codes were not included in this Change Request.

In 2011, Change Request 7277 said that the HCPCS code 88172 [Cytopathology, evaluation of fine needle aspirate; immediate cytohistologic study to determine adequacy for diagnosis, first evaluation episode, each site] and HCPCS code 88177 [Cytopathology, evaluation of fine needle aspirate; immediate cytohistologic study to determine adequacy for diagnosis, each separate additional evaluation episode, same site (list separately in addition to code for primary procedure)] were not subject to CLIA edits and did not require a facility to have any CLIA certificate. CMS has received information from a laboratory professional society

that these codes should be subject to CLIA edits. CMS concurs with their opinion. Hence, effective January 1, 2013, HCPCS codes 88172 and 88177, including the modifiers TC and 26, will be subject to CLIA edits and require a facility to have a CLIA certificate.

This Recurring Update Notification applies to Chapter 16, Section 70.9.

**B. Policy:** The CLIA regulations require a facility to be appropriately certified for each test performed. To ensure that Medicare and Medicaid only pay for laboratory tests in a facility with a valid, current CLIA certificate, laboratory claims are currently edited at the CLIA certificate level.

**II. BUSINESS REQUIREMENTS TABLE**

Use "Shall" to denote a mandatory requirement.

Number	Requirement	Responsibility										
		A/B MAC		D M E M A C	F I	C A R R I E R	R H I	Shared-System Maintainers				Other
		P a r t A	P a r t B					F I S S	M C S	V M S	C W F	
8162.1	Contractors shall apply CLIA edits to the HCPCS codes mentioned above as subject to CLIA edits.		X			X					X	
8162.2	Contractors shall deny payment for a claim submitted with the HCPCS codes mentioned above as subject to CLIA edits to a provider without valid current CLIA certificate, with a CLIA certificate of waiver (certificate type code 2), or with a CLIA certificate for provider-performed microscopy procedures (certificate type code 4).		X			X						
8162.3	Contractors shall return a claim as unprocessable if a CLIA number is not submitted on claims by providers for the HCPCS mentioned above as subject to CLIA edits.		X			X						
8162.4	Contractors need not search their files to either retract payment for claims already paid or to retroactively pay claims. However, contractors shall adjust claims brought to their attention.		X			X						

### III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility					
		A/ B M A C	D M E M A C	FI	C A R R I E R	R H H I	Other
		Pa r t A	P a r t B				
8162.5	MLN Article: A provider education article related to this instruction will be available at <a href="http://www.cms.hhs.gov/MLNMattersArticles/">http://www.cms.hhs.gov/MLNMattersArticles/</a> shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web sites and include information about it in a listserv message within one week of the availability of the provider education article. In addition, the provider education article shall be included in the contractor's next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.		X			X	

### IV. SUPPORTING INFORMATION

**Section A: Recommendations and supporting information associated with listed requirements: N/A**  
 Use "Should" to denote a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

**Section B: All other recommendations and supporting information: N/A**

### V. CONTACTS

**Pre-Implementation Contact(s):** Kathleen Todd, 410-786-3385 or kathleen.todd@cms.hhs.gov

**Post-Implementation Contact(s):** Contact your Contracting Officer's Representative (COR) or Contractor Manager, as applicable.

## **VI. FUNDING**

### **Section A: For Fiscal Intermediaries (FIs), Regional Home Health Intermediaries (RHHIs), and/or Carriers:**

No additional funding will be provided by CMS; Contractors activities are to be carried out with their operating budgets.

### **Section B: For Medicare Administrative Contractors (MACs):**

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS do not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

Attachment

## MOLECULAR HCPCS CODES FROM 2012

HCPCS	Description
81200	ASPA (aspartoacylase) (e.g., Canavan disease) gene analysis, common variants (e.g., E285, Y231X)
81205	BCKDHB (branched-chain keto acid dehydrogenase E1, beta polypeptide) (e.g., Maple syrup urine disease) gene analysis, common variants (EG, R183P, G278S, E422X)
81206	BCR/ABL1 (t(9;22)) (e.g., chronic myelogenous leukemia) translocation analysis; major breakpoint qualitative or quantitative
81207	BCR/ABL1 (t(9;22)) (e.g., chronic myelogenous leukemia) translocation analysis; minor breakpoint, qualitative or quantitative
81208	BCR/ABL1 (t(9;22)) (e.g., chronic myelogenous leukemia) translocation analysis; other breakpoint, qualitative or quantitative
81209	BLM (Bloom syndrome, RecQ helicase-like) (e.g., Bloom syndrome) gene analysis, 2281del6ins7 variant
81210	BRAF (v-raf murine sarcoma viral oncogene homolog B1) (e.g., colon cancer), gene analysis, V600E variant
81211	BRCA1, BRCA2 (breast cancer 1 and 2)(e.g., hereditary breast and ovarian cancer) gene analysis; full sequence analysis and common duplication/deletion variants in BCRA1 (i.e., exon 13 del 3.835kb, exon 13 dup 6kb, exon 14-20 del 26kb, exon 22 del 510bp, exon 8-9 del 7.1kb)
81212	BRCA1, BRCA2 (breast cancer 1 and 2)(e.g., hereditary breast and ovarian cancer) gene analysis; 185delAG, 5385insC, 6174delT variants
81213	BRCA1, BRCA2 (breast cancer 1 and 2)(e.g., hereditary breast and ovarian cancer) gene analysis; uncommon duplication/deletion variants
81214	BRCA1 (breast cancer 1) (e.g., hereditary breast and ovarian cancer) gene analysis; full sequence analysis and common duplication/deletion variants, (i.e., exon 13 del 3.835kb, exon 13 dup 6kb, exon 14-20 del 26kb, exon 22 del 510bp, exon 8-9 del 7.1kb )
81215	BRCA1 (breast cancer 1) (e.g., hereditary breast and ovarian cancer) gene analysis; known familial variant
81216	BRCA2 (breast cancer 2) (e.g., hereditary breast and ovarian cancer) gene analysis; full sequence analysis
81217	BRCA2 (breast cancer 2) (e.g., hereditary breast and ovarian cancer) gene analysis; known familial variant
81220	CFTR (cystic fibrosis transmembrane conductance regulator) (e.g., cystic fibrosis) gene analysis; common variants (e.g., ACMG/ACOG guidelines)
81221	CFTR (cystic fibrosis transmembrane conductance regulator) (e.g., cystic fibrosis) gene analysis; known familial variants
81222	CFTR (cystic fibrosis transmembrane conductance regulator) (e.g., cystic fibrosis) gene analysis; duplication/deletion variants
81223	CFTR (cystic fibrosis transmembrane conductance regulator) (e.g., cystic fibrosis) gene analysis; full gene sequence

<b>HCPCS</b>	<b>Description</b>
81224	CFTR (cystic fibrosis transmembrane conductance regulator) (e.g., cystic fibrosis) gene analysis; intron 8 poly-T analysis (e.g., male infertility)
81225	CYP2C19 (cytochrome P450, family 2, subfamily C, polypeptide 19) (e.g., drug metabolism), gene analysis, common variants (e.g., *2; *3,*4, *8, *17)
81226	CYP2D6 (cytochrome P450, family 2, subfamily D, polypeptide 6)(e.g., drug metabolism), gene analysis, common variants (e.g., *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) (e.g., drug metabolism), gene analysis, common variants (e.g., *2, *3, *5, *6)
81228	Cytogenomic constitutional (genome-wide) microarray analysis; interrogation of genomic regions for copy number variants (e.g., Bacterial Artificial Chromosome [BAC] or oligo-based comparative genomic hybridization [CGH] microarray analysis)
81229	Cytogenomic constitutional (genome-wide) microarray analysis; interrogation of genomic regions for copy number and single nucleotide polymorphism (SNP) variants for chromosomal abnormalities
81240	F2 (prothrombin, coagulation factor II) (e.g., hereditary hypercoagulability) gene analysis, 2021OG>A variant
81241	F5(coagulation Factor V) (e.g., hereditary hypercoagulability) gene analysis, Leiden variant
81242	FANCC (Fanconi anemia, complementation group C)(e.g., Fanconi anemia, type C) gene analysis, common variant (e.g., IVS4+4A>T)
81243	FMR1 (Fragile X mental retardation 1) (e.g., fragile X mental retardation) gene analysis; evaluation to detect abnormal (e.g., expanded) alleles
81244	FMR1 (Fragile X mental retardation 1) (e.g., fragile X mental retardation) gene analysis; characterization of alleles (e.g., expanded size and methylation status)
81245	FLT3 (fms-related tyrosine kinase 3) (e.g., acute myeloid leukemia), gene analysis, internal tandem duplication (ITD) variants (i.e., exon 14, 15)
81250	G6PC (glucose-6-phosphatase, catalytic subunit) (e.g., Glycogen, storage disease, Type 1a, von Gierke disease) gene analysis, common variants (e.g., R83C, Q347X)
81251	GBA (glucosidase, beta acid) (e.g., Gaucher, disease) gene analysis, common variants (e.g., N370S, 84GG, L444P, IVS2+1G>A)
81255	HEXA (hexosaminidase A[alpha polypeptide]) (e.g., Tay-Sachs disease) gene analysis, common variants (e.g., 1278insTATC, 1421 +1G>C, G269S)
81256	HFE (hemochromatosis) (e.g., hereditary hemochromatosis) gene analysis, common variants (e.g., C282Y, H63D)

HCPCS	Description
81257	HBA1/HBA2 (alpha globin 1 and alpha globin 2) (e.g., alpha thalassemia, Hb Bart hydrops fetalis syndrome, HbH disease), gene analysis, for common deletions or variant (e.g., Southeast Asian, Thai, Filipino, Mediterranean, alpha3.7, alpha4.2, alpha20.5, and Constant Spring)
81260	IKBKAP (inhibitor of kappa light polypeptide gene enhancer in B-cells, kinase complex-associated protein) (e.g., familial dysautonomia) gene analysis, common variants (e.g., 2507+6T>C, R696P)
81261	IGH@(Immunoglobulin heavy chain locus)(e.g., leukemias and lymphomas, B-cell), gene rearrangement analysis to detect abnormal clonal population(s); amplified methodology (e.g., polymerase chain reaction)
81262	IGH@(Immunoglobulin heavy chain locus)(e.g., leukemias and lymphomas, B-cell), gene rearrangement analysis to detect abnormal clonal population(s); direct probe methodology (e.g., Southern blot)
81263	IGH@(Immunoglobulin heavy chain locus)(e.g., leukemia and lymphoma, B-cell), variable region somatic mutation analysis
81264	IGK@(Immunoglobulin kappa light chain locus)(e.g., leukemia and lymphoma, B-cell), gene rearrangement analysis, evaluation to detect abnormal clonal population(s)
81265	Comparative analysis using Short Tandem repeat (STR) markers; patient and comparative specimen (e.g., pre-transplant recipient and donor germline testing, post-transplant non-hematopoietic recipient germline [e.g., buccal swab or other germline tissue sample] and donor testing, twin zygosity testing, or maternal cell contamination of fetal cells)
81266	Comparative analysis using Short Tandem repeat (STR) markers; each additional specimen (e.g., additional cord blood donor, additional fetal samples from different cultures, or additional zygosity in multiple birth pregnancies)(List separately in addition to code for primary procedure)
81267	Chimerism (engraftment) analysis, post transplantation specimen (e.g., hematopoietic stem cell), includes comparison to previously performed baseline analyses; without cell selection
81268	Chimerism (engraftment) analysis, post transplantation specimen (e.g., hematopoietic stem cell), includes comparison to previously performed baseline analyses; with cell selection (e.g., CD3, CD33), each cell type
81270	JAK2 (Janus kinase 2) (e.g., myeloproliferative disorder), gene analysis, p.Val617Phe(V617F) variant
81275	KRAS (v-Ki-ras2 Kirsten rat sarcoma viral oncogene) (e.g., carcinoma), gene analysis, variants in codons 12 and 13
81280	Long QT syndrome gene analysis (e.g., KCNQ1, KCNH2, SCN5A, KCNE1, KCNE2, KCNJ2, CACNA1C, CAV3, SCN4B, AKAP, SNTA1, and ANK2); full sequence analysis
81281	Long QT syndrome gene analysis (e.g., KCNQ1, KCNH2, SCN5A, KCNE1, KCNE2, KCNJ2, CACNA1C, CAV3, SCN4B, AKAP, SNTA1, and ANK2); known familial sequence variant

<b>HCPCS</b>	<b>Description</b>
81282	Long QT syndrome gene analysis (e.g., KCNQ1, KCNH2, SCN5A, KCNE1, KCNE2, KCNJ2, CACNA1C, CAV3, SCN4B, AKAP, SNTA1, and ANK2); duplication/deletion variants
81290	MCOLN1 (mucolipin 1)(eg., Mucopolipidosis, type IV) gene analysis, common variants (e.g., IVS3-2A>G, del6.4kb)
81291	MTHFR (5, 10-methylenetetrahydrofolate, reductase)(e.g., hereditary hypercoagulability) gene analysis, common variants (e.g., 677T, 1298C)
81292	MLH1 (mutL homolog 1, colon cancer, nonpolyposis type 2)(e.g., hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; full sequence analysis
81293	MLH1 (mutL homolog 1, colon cancer, nonpolyposis type 2)(e.g., hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; known familial variants
81294	MLH1 (mutL homolog 1, colon cancer, nonpolyposis type 2)(e.g., hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; duplication/deletion variants
81295	MSH2 (mutS homolog 2, colon cancer, nonpolyposis type 1)(e.g., hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; full sequence analysis
81296	MSH2 (mutS homolog 2, colon cancer, nonpolyposis type 1)(e.g., hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; known familial variants
81297	MSH2 (mutS homolog 2, colon cancer, nonpolyposis type 1)(e.g., hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; duplication/deletion variants
81298	MSH6 (mutS homolog 6 [E. coli]) (e.g., hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; full sequence analysis
81299	MSH6 (mutS homolog 6 [E. coli]) (e.g., hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; known familial variants
81300	MSH6 (mutS homolog 6 [E. coli]) (e.g., hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; duplication/deletion variants
81301	Microsatellite instability analysis (e.g., hereditary non-polyposis colorectal cancer, Lynch syndrome) of markers for mismatch repair deficiency (eg, BAT25, BAT26), includes comparison of neoplastic and normal tissue, if performed
81302	MECP2 (methyl CpG binding protein 2) (e.g., Rett syndrome) gene analysis; full sequence analysis
81303	MECP2 (methyl CpG binding protein 2) (e.g., Rett syndrome) gene analysis; known familial variant
81304	MECP2 (methyl CpG binding protein 2) (e.g., Rett syndrome) gene analysis; duplication/deletion variants
81310	NPM1 (nucleophosmin)(e.g., acute myeloid leukemia) gene analysis, exon 12 variants

<b>HCPCS</b>	<b>Description</b>
81315	PML/RaRalpha, (t(15;17)), (promyelocytic leukemia/retinoic acid receptor alpha)(e.g., promyelocytic leukemia) translocation analysis; common breakpoints (e.g., intron 3 and intron 6), qualitative or quantitative
81316	PML/RaRalpha, (t(15;17)), (promyelocytic leukemia/retinoic acid receptor alpha)(e.g., promyelocytic leukemia) translocation analysis; single breakpoint (e.g., intron 3, intron 6 or exon 6), qualitative or quantitative
81317	PMS2 (postmeiotic segregation increased 2 [ <i>S. cerevisiae</i> ]) (e.g., hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; full sequence
81318	PMS2 (postmeiotic segregation increased 2 [ <i>S. cerevisiae</i> ]) (e.g., hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; known familial variants
81319	PMS2 (postmeiotic segregation increased 2 [ <i>S. cerevisiae</i> ]) (e.g., hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; duplication/deletion variants
81330	SMPD1(sphingomyelin phosphodiesterase 1, acid lysosomal) (e.g., Niemann-Pick disease, Type A) gene analysis, common variants (e.g., R496L, L302P, fsP330)
81331	SNRPN/UBE3A (small nuclear ribonucleoprotein polypeptide N and ubiquitin protein ligase E3A) (e.g., Prader-Willi syndrome and/or Angelman syndrome), methylation analysis
81332	SERPINA1 (serpin peptidase inhibitor, clade A, alpha-1 antiproteinase, antitrypsin, member 1) (e.g., alpha-1-antitrypsin deficiency), gene analysis, common variants (e.g., *S and *Z)
81340	TRB@ (T cell antigen receptor, beta) (e.g., leukemia and lymphoma), gene rearrangement analysis to detect abnormal clonal population(s); using amplification methodology (e.g., polymerase chain reaction)
81341	TRB@ (T cell antigen receptor, beta) (e.g., leukemia and lymphoma), gene rearrangement analysis to detect abnormal clonal population(s); using direct probe methodology (e.g., Southern blot)
81342	TRG@ (T cell antigen receptor, gamma)(e.g., leukemia and lymphoma), gene rearrangement analysis; evaluation to detect abnormal clonal population(s)
81350	UGT1A1 (UDP glucuronosyltransferase 1 family, polypeptide A1) (e.g., irinotecan metabolism), gene analysis, common variants (e.g., *28, *36, *37)
81355	VKORC1 (vitamin K epoxide reductase complex. subunit 1) (e.g., warfarin metabolism), gene analysis, common variants (e.g., -1639/3673)
81370	HLA Class I and II typing, low resolution (e.g., antigen equivalents); HLA-A, -B -C, -DRB1/3/4/5, and -DQB1
81371	HLA Class I and II typing, low resolution (e.g., antigen equivalents); HLA-A, -B, and -DRB1/3/4/5 (e.g., verification typing)

<b>HCPCS</b>	<b>Description</b>
81372	HLA Class I typing, low resolution (e.g., antigen equivalents); complete (i.e., HLA-A, -B, and -C)
81373	HLA Class I typing, low resolution (e.g., antigen equivalents); one locus (e.g., HLA-A, -B, or -C), each
81374	HLA Class I typing, low resolution (e.g., antigen equivalents); one antigen equivalent (e.g., B*27), each
81375	HLA Class II typing, low resolution (e.g., antigen equivalents); HLA-DRB1/3/4/5 and -DQB1
81376	HLA Class II typing, low resolution (e.g., antigen equivalents); one locus (e.g., HLA-DRB1/3/4/5, -DQB1, -DQA1, -DPB1, or -DPA1), each
81377	HLA Class II typing, low resolution (e.g., antigen equivalents); one antigen equivalent, each
81378	HLA Class I and II typing, high resolution (i.e., alleles or allele groups), HLA-A, -B, -C, and -DRB1
81379	HLA Class I typing, high resolution (i.e., alleles or allele groups); complete (i.e., HLA-A, -B, and -C)
81380	HLA Class I typing, high resolution (i.e., alleles or allele groups); one locus (e.g., HLA-A, -B, or -C), each
81381	HLA Class I typing, high resolution (i.e., alleles or allele groups); one allele or allele group (e.g., B*57:01P), each
81382	HLA Class II typing, high resolution (i.e., alleles or allele groups); one locus (e.g., HLA-DRB1, -DRB3, -DRB4, -DRB5, -DQB1, -DQA1, -DPB1, or -DPA1), each
81383	HLA Class II typing, high resolution (i.e., alleles or allele groups); one allele or allele group (e.g., HLA-DQB1*06:02P), each
81400	Molecular pathology procedure, Level 1 (e.g., identification of single germline variant [e.g., SNP] by techniques such as restriction enzyme digestion or melt curve analysis)
81401	Molecular pathology procedure, Level 2 (e.g., 2-10 SNPs, 1 methylated variant, or 1 somatic variant [typically using nonsequencing target variant analysis], or detection of a dynamic mutation disorder/triplet repeat)
81402	Molecular pathology procedure, Level 3 (e.g., >10 SNPs, 2-10 methylated variants, or 2-10 somatic variants [typically using non-sequencing target variant analysis], immunoglobulin and T-cell receptor gene rearrangements, duplication/deletion variants 1 exon)
81403	Molecular pathology procedure, Level 4 (e.g., analysis of single exon by DNA sequence analysis, analysis of >10 amplicons using multiplex PCR in 2 or more independent reactions, mutation scanning or duplication/deletion variants of 2-5 exons)
81404	Molecular pathology procedure, Level 5 (e.g., analysis of 2-5 exons by DNA sequence analysis, mutation scanning or duplication/deletion variants of 6-10 exons, or characterization of a dynamic mutation disorder/triplet repeat by Southern blot analysis)

<b>HCPCS</b>	<b>Description</b>
81405	Molecular pathology procedure, Level 6 (e.g., analysis of 6-10 exons by DNA sequence analysis, mutation scanning or duplication/deletion variants of 11-25 exons)
81406	Molecular pathology procedure, Level 7 (e.g., analysis of 11-25 exons by DNA sequence analysis, mutation scanning or duplication/deletion variants of 26-50 exons, cytogenomic array analysis for neoplasia)
81407	Molecular pathology procedure. Level 8 (e.g., analysis of 26-50 exons by DNA sequence analysis, mutation scanning or duplication/deletion variants of >50 exons, sequence analysis of multiple genes on one platform)
81408	Molecular pathology procedure, Level 9 (e.g., analysis of >50 exons in a single gene by DNA sequence analysis)