# Local Coverage Determination (LCD): Molecular Pathology Procedures (L35000)

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# Contractor Information

| Contractor Name | Contract Type | Contract Number | Jurisdiction | State(s) |
|---|---|---|---|---|
| National Government Services, Inc. | MAC - Part A | 06101 - MAC A | N/A | Illinois |
| National Government Services, Inc. | MAC - Part B | 06102 - MAC B | N/A | Illinois |
| National Government Services, Inc. | MAC - Part A | 06201 - MAC A | N/A | Minnesota |
| National Government Services, Inc. | MAC - Part B | 06202 - MAC B | N/A | Minnesota |
| National Government Services, Inc. | MAC - Part A | 06301 - MAC A | N/A | Wisconsin |
| National Government Services, Inc. | MAC - Part B | 06302 - MAC B | N/A | Wisconsin |
| National Government Services, Inc. | A and B and HHH MAC | 13101 - MAC A | J - K | Connecticut |
| National Government Services, Inc. | A and B and HHH MAC | 13102 - MAC B | J - K | Connecticut |
| National Government Services, Inc. | A and B and HHH MAC | 13201 - MAC A | J - K | New York - Entire State |
| National Government Services, Inc. | A and B and HHH MAC | 13202 - MAC B | J - K | New York - Downstate |
| National Government Services, Inc. | A and B and HHH MAC | 13282 - MAC B | J - K | New York - Upstate |
| National Government Services, Inc. | A and B and HHH MAC | 13292 - MAC B | J - K | New York - Queens |
| National Government Services, Inc. | A and B and HHH MAC | 14111 - MAC A | J - K | Maine |
| National Government Services, Inc. | A and B and HHH MAC | 14112 - MAC B | J - K | Maine |
| National Government Services, Inc. | A and B and HHH MAC | 14211 - MAC A | J - K | Massachusetts |
| National Government Services, Inc. | A and B and HHH MAC | 14212 - MAC B | J - K | Massachusetts |
| National Government Services, Inc. | A and B and HHH MAC | 14311 - MAC A | J - K | New Hampshire |
| National Government Services, Inc. | A and B and HHH MAC | 14312 - MAC B | J - K | New Hampshire |
| National Government Services, Inc. | A and B and HHH MAC | 14411 - MAC A | J - K | Rhode Island |
| National Government Services, Inc. | A and B and HHH MAC | 14412 - MAC B | J - K | Rhode Island |
| National Government Services, Inc. | A and B and HHH MAC | 14511 - MAC A | J - K | Vermont |
| National Government Services, Inc. | A and B and HHH MAC | 14512 - MAC B | J - K | Vermont |

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# LCD Information

## Document Information

| LCD ID | Original Effective Date |
|---|---|

L35000

For services performed on or after 10/01/2015

LCD Title
Molecular Pathology Procedures

Revision Effective Date
For services performed on or after 02/01/2017



Revision Ending Date
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Retirement Date
N/A

Notice Period Start Date
10/13/2016

Notice Period End Date
11/30/2016

CMS National Coverage Policy Language quoted from Centers for Medicare and Medicaid Services (CMS), National Coverage Determinations (NCDs) and coverage provisions in interpretive manuals is italicized throughout the policy. NCDs and coverage provisions in interpretive manuals are not subject to the Local Coverage Determination (LCD) Review Process (42 CFR 405.860[b] and 42 CFR 426 [Subpart D]). In addition, an administrative law judge may not review an NCD. See Section 1869(f)(1)(A)(i) of the Social Security Act.

Unless otherwise specified, *italicized* text represents quotation from one or more of the following CMS sources:

Title XVIII of the Social Security Act (SSA):
Section 1862(a)(1)(A) excludes expenses incurred for items or services which are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

Section 1833(e) prohibits Medicare payment for any claim which lacks the necessary information to process the claim.

Section 1862(a)(7) excludes routine physical examinations, unless otherwise covered by statute.

CMS Publications:
CMS Publication 100-02, *Medicare Benefit Policy Manual*, Chapter 15, Section 80.1 – Laboratory services must meet applicable requirements of CLIA

CMS Publication 100-04, *Medicare Claims Processing Manual*, Chapter 16, Section 40.7 Billing for Noncovered Clinical Laboratory Tests Section and 120.1 Clarification of the Use of the Term "Screening" or "Screen"

CMS Publication 100-04, *Medicare Claims Processing Manual*, Chapter 30, Section 50 Advance Beneficiary Notice of Noncoverage (ABN)

CMS Publication 100-08, *Medicare Program Integrity Manual*, Chapter 13, Local Coverage Determinations

CMS National Correct Coding Initiative (NCCI) *Policy Manual for Medicare Services*, Chapter 10, Pathology/Laboratory Services, (A) Introduction

CMS Publication 100-02, *Medicare Benefit Policy Manual*, Chapter 15, Section 80.6. 5 which describes the Surgical/Cytopathology Exception.

CMS National Correct Coding Initiative (NCCI) *Policy Manual for Medicare Services*, Chapter 10 Pathology/Laboratory Services which addresses reflex testing.

Code of Federal Regulations:
42 CFR, Section 410.32, indicates that diagnostic tests may only be ordered by the treating physician (or other treating practitioner acting within the scope of his or her license and Medicare requirements) who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem. Tests not ordered by the physician (or other qualified non-physician provider) who is treating the beneficiary are not reasonable and necessary (see Sec. 411.15(k)(1) of this chapter).

Coverage Guidance
**Coverage Indications, Limitations, and/or Medical Necessity**

**Abstract:**
According to The American Medical Association (AMA) Current Procedural Terminology (CPT) manual, molecular pathology procedures are medical laboratory procedures involving the analyses of nucleic acid to detect variants in genes that may be indicative of germline (e.g., constitutional disorders) or somatic (e.g., neoplasia) conditions, or to test for histocompatibility antigens (e.g., HLA). Given the elimination of the stacking procedure codes (83890-83914) and the array based evaluation codes (88384-88386), molecular pathology codes now include all analytical services performed in the test (e.g., cell lysis, nucleic acid stabilization, extraction, digestion, amplification, and detection). (Note: molecular pathology procedure techniques may be described in other sections of the Pathology and Laboratory section of CPT. For microbial identification using molecular pathology techniques CPT codes 87149-87153, 87470-87801, and 87900-87904 apply. For in situ hybridization analyses, CPT codes 88271-88275 and 88365-88368 apply.)

Code selection is typically based on the specific gene(s) that is being analyzed. Codes that describe tests to assess for the presence of gene variants use common gene variant names. Typically, all of the listed variants would be tested. However, these lists are not exclusive. If other variants are also tested in the analysis, they would be included in the procedure and not reported separately. Full gene sequencing should not be reported using codes that assess for the presence of gene variants unless the CPT code specifically states full gene sequence in the code descriptor. In other words, you may only assign the CPT code that is described as “full gene sequence” if the test assay performed was a full gene sequence.

There are Tier 1 and Tier 2 molecular pathology procedure codes. Tier 1 codes generally describe testing for a specific gene or HLA locus. Tier 2 molecular pathology procedures represent procedures that are generally performed in lower volumes than Tier 1 molecular pathology procedures (e.g., the incidence of the disease being tested is rare). They are arranged by level of technical resources and interpretive work by the physician or other qualified healthcare professional. If the gene tested is not listed under one of the Tier 2 codes or is not represented by a Tier 1 code in CPT, use of the unlisted CPT code 81479 is required.

Molecular pathology procedures have broad clinical and research applications. The following examples of applications may not be relevant to a Medicare beneficiary or may not meet a Medicare benefit category and/or reasonable and necessary threshold for coverage. Such examples include Genetic Testing and Genetic Counseling (when applicable) for:

- Disease Risk,
- Carrier Screening,
- Hereditary Cancer Syndromes,
- Gene Expression Profiling for certain cancers,
- Prenatal Diagnostic testing,
- Diagnosis and Monitoring Non-Cancer Indications, and
- Several Pharmacogenomic applications.

Based on the Centers for Medicare & Medicaid Services (CMS) Program Integrity Manual (100-08), this Local Coverage Determination (LCD) addresses the circumstances under which the item or service may be reasonable and necessary under the Social Security Act, §1862(a)(1)(A). For laboratory services, a service may be reasonable and necessary if the service is safe and effective; and appropriate, including the duration and frequency that is considered appropriate for the item or service, in terms of whether it is furnished in accordance with accepted standards of medical practice for the diagnosis of the patient's condition; furnished in a setting appropriate to the patient's medical needs and condition; ordered and furnished by qualified personnel; one that

meets, but does not exceed, the patient's medical need; and is at least as beneficial as an existing and available medically appropriate alternative.

Per 42 Code of Federal Regulations (CFR) section 410.32 (a) the following requirements must be met for coverage: *All diagnostic x-rays tests, diagnostic laboratory tests, and other diagnostic tests must be ordered by the physician who is treating the beneficiary, that is, the physician who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem. Tests not ordered by the physician who is treating the beneficiary are not reasonable and necessary (see §411.15(k)(1)).* Also, see Medicare Benefit Policy Manual (100-02), Chapter 15, Section 80.6 for related physician order instructions.

*Laboratory services must meet all applicable requirements of the Clinical Laboratory Improvement Amendments of 1988 (CLIA), as set forth at 42 CFR part 493. Section 1862(a)(1)(A) of the Act provides that Medicare payment may not be made for services that are not reasonable and necessary. Clinical laboratory services must be ordered and used promptly by the physician who is treating the beneficiary as described in 42 CFR 410.32(a), or by a qualified nonphysician practitioner, as described in 42 CFR 410.32(a)(3).*

Many applications of the molecular pathology procedures are not covered services given lack of benefit category (e.g., preventive service or screening for a genetic abnormality in the absence of a suspicion of disease) and/or failure to the reasonable and necessary threshold for coverage (e.g., based on quality of clinical evidence and strength of recommendation or when the results would not reasonably be used in the management of a beneficiary). Furthermore, payment of claims in the past (based on stacking codes) or in the future (based on the new code series) is not a statement of coverage since the service may not have been audited for compliance with program requirements and documentation supporting the reasonable and necessary testing for the beneficiary. Certain molecular pathology procedures may be subject to prepayment medical review (records requested) and paid claims must be supportable, if selected, for post payment audit by the MAC or other contractors. Molecular pathology tests for diseases or conditions that manifest severe signs or symptoms in newborns and in early childhood or that result in early death (e.g., Canavan disease) could be subject to automatic denials since these tests are not usually relevant to a Medicare beneficiary.

This LCD gives general guidance to the medically reasonable and necessary applications of the Molecular Pathology Procedures and Genomic Sequencing Procedures, described in Current Procedural Terminology (CPT).

**Indications:**
Molecular pathology procedures (Tier1 and Tier 2) may be eligible for coverage when **ALL** of the following criteria are met:

- Alternative laboratory or clinical tests to definitively diagnose the disorder/identify the condition are unavailable or results are clearly equivocal; AND
- Availability of a clinically valid test, based on published peer reviewed medical literature; AND
- Testing assay(s) are Food and Drug Administration (FDA) approved/cleared or if LDT (lab developed test) or LDT protocol or FDA modified test(s) the laboratory documentation should support assay(s) of analytical validity and clinical utility; AND
- Results of the testing must directly impact treatment or management of the Medicare beneficiary; AND
- For testing panels, including but not limited to, multiple genes or multiple conditions, and in cases where a tiered approach/method is clinically available, testing would be covered ONLY for the number of genes or test that are reasonable and necessary to obtain necessary information for therapeutic decision making; AND
- Individual has not previously received genetic testing for the disease/condition. (In general, diagnostic genetic testing for a disease should be performed once in a lifetime.) Exceptions include clinical scenarios whereby repeat testing of somatically-acquired mutations (for example, pre- and post- therapy) may be required to inform appropriate therapeutic decision-making.

**Limitations:**

• Any procedures required prior to cell lysis (e.g., microdissection [CPT codes 88380 and 88381]) should be reported separately and utilization must be clearly supported based on the application and clinical utility. Such claims may be subject to prepayment medical review.
• HCPCS code G0452 describes the medically necessary interpretation and report of a molecular pathology test, written by a pathologist, which is above and beyond the report of standard laboratory results. Non-physician practitioners (e.g., PhD, scientists etc.) are not eligible to report this code; only physicians may use/bill this code.
• Testing for quality assurance [component of the service is not separately billable per CMS National Correct Coding Initiative (NCCI)].

**INDICATIONS AND LIMITATIONS OF COVERAGE BY CPT CODE**

**CPT Code 81170**

ABL1 (ABL proto-oncogene 1, non-receptor tyrosine kinase) (eg, acquired imatinib tyrosine kinase inhibitor resistance), gene analysis, variants in the kinase domain is considered medically necessary in patients with acute lymphoblasic leukemia (ALL) and chronic myeloid leukemia (CML) to guide therapeutic decision making.

**CPT Codes 81206, 81207, and 81208**

BCR/ABL is considered medically necessary in the evaluation of individuals with chronic myelogenous leukemia or BCR-ABL positive acute lymphoblastic leukemia to evaluate treated individuals who manifest suboptimal response to initial tyrosine kinase inhibitor therapy or loss of response to tyrosine kinase inhibitor therapy.

**CPT Code 81209**

BLM (Bloom syndrome, RecQ helicase-like)(e.g. Bloom syndrome) gene analysis, 2281 del6ins7 variant is considered medically necessary for a beneficiary who may have Bloom syndrome to confirm diagnosis and guide medical decision-making.

**CPT Code 81210**

BRAF gene analysis is considered medically necessary for patients who have malignant melanoma, non-small cell lung cancer, hairy cell leukemia, or metastatic colorectal cancer when needed to determine if a Medicare covered therapy is a reasonable option given the individual's specific clinical presentation.

**CPT Codes 81162, 81211, 81212, 81213, 81214, 81215, 81216, 81217**

BRCA1 and BRCA2 genetic testing is considered medically necessary for a beneficiary with a personal history of a cancer associated with the BRCA mutation who meets one or more of the criteria found in the most recent version of the NCCN guidelines for **Genetic/Familial High-Risk Assessment: Breast and Ovarian** or other evidence based guideline addressing genetic testing.

**CPT Code 81218**

CEBPA (CCAAT/enhancer binding protein [C/EBP], alpha) (eg, acute myeloid leukemia), full gene sequence is considered medically necessary in patients with acute myelogenous leukemia (AML) to guide therapeutic decision making.

**CPT Code 81219**

CALR (calreticulin) (eg, myeloproliferative disorders), gene analysis, common variants in exon 9 is considered medically necessary in the initial diagnostic work-up of BCR-ABL negative, JAK2-negative adults with clinical, laboratory, or pathological findings suggesting polycythemia vera (PV), essential thrombocythemia (ET) or primary myelofibrosis (PMF).

**CPT Codes 81220, 81221, 81222, 81223, 81224**

CFTR (cystic fibrosis transmembrane conductance regulator) (e.g.cystic fibrosis) gene analysis, common variants (e.g. ACMG/ACOG guidelines) is considered medically necessary for a beneficiary who has or may have cystic fibrosis to guide therapeutic decision-making.

**CPT Code 81225**

CYP2C6 19-cytochrome P450 CYP2C6 19-cytochrome P450
Based on the FDA's Black Box warning for clopidogrel, the effectiveness of clopidogrel is dependent on its activation to an active metabolite by the cytochrome P450 (CYP) system, principally CYP2C19.

CYP2C619 genotyping may be medically necessary once per lifetime to identify individuals:

- Who are poor metabolizers of clopidogrel, so that alternative treatment or treatment strategies can be considered.

- Who are poor metabolizers of clopidogrel with acute coronary syndrome or who are undergoing percutaneous coronary intervention.

**CPT Code 81226**
CYP2D6 (cytochrome P450, family 2, subfamily D polypeptide 6) (e.g., drug metabolism), gene analysis, is only considered medically necessary for individuals with Huntington's disease for whom doses of tetrabenazine greater than 50 mg per day are being considered, and for testing prior to the initiation of Cerdelga™ (eliglustat) for Gaucher's disease.

**CPT Code 81227 Use only G9143 CYP2C9 and/or VKORC1 Gene Testing for Warfarin Response**
Pharmacogenomic Testing for Warfarin Response, gene testing on CYP2C9 and/or VKORC1 see NCD 90.1 for coverage information.

**CPT Code 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) [when specified as EGFR mutation analysis testing]

EGFR testing is considered medically necessary as a technique to predict treatment response for individuals with non-small cell lung cancer undergoing treatment with EGFR tyrosine kinase inhibitor (TKI) therapy (for example, erlotinib [Tarceva® ], gefitinib [Iressa® ], or afatinib [Gilotrif® ]).

**CPT Code 81240 and 81241**
F2 gene (prothrombin coagulation factor II) and F5 gene (coagulation factor V)

The F2 and F5 genetic tests are not considered to be clinically efficacious; therefore, testing is not medically necessary.

**CPT Codes 81245, 81246**
The FLT3 is considered medically necessary in patients with acute myeloid leukemia (AML) to guide therapeutic decision making.

**CPT code 81256**
The HFE (hemochromatosis)(hereditary hemochrosis) gene analysis, common variants (e.g. C282Y, H63D) is considered medically necessary in patients with iron overload of uncertain etiology (e.g. when the test is used to avoid liver biopsy in someone when the ferritin and the transferrin saturation are elevated greater than 45%). The genotyping of patients with iron overload of uncertain etiology is allowed only once per lifetime.

**CPT codes 81261-81264**
The IGH@ (Immunoglobulin heavy chain locus) is considered medically necessary for acute myeloid leukemia (AML) and lymphoma, B-cell to guide therapeutic decision making.

**CPT codes 81265-81268**
Chimerism analysis to identify appropriate donors and monitor engraftment success or disease reoccurrence is considered medically necessary.

CPT code 81265 includes donor and recipient testing and should be reported with one unit of service. Except in rare cases, this service would only be performed once per lifetime.

CPT code 81266 describes a service that may be used for two different reasons: additional births and bone marrow transplant. When used in bone marrow transplants to report an additional double-cord blood sample, it is a covered service. Since its use to report multiple births would be atypical for the Medicare population, it would not be a covered service.

CPT code 81267 is considered medically necessary in patients with diagnoses of leukemia and lymphomas and should be used post transplantation to confirm successful engraftment or disease reoccurrence. Although the original donor specimen may be referenced, an additional 81265 should not be submitted in addition to the 81267 service. For labs that hold the pre-transplant specimen (81265 and/or 81266) until after the transplant occurs, use 81267 plus 81265 and 81266 if necessary.

CPT code 81267 may be reported for the findings of the pre and post-transplant comparison.

CPT code 81268 may be used to report chimerism using a buccal or other germline tissue specimen from the recipient post-transplantation. For laboratories that hold the pre-transplant specimen (81265 and/or 81266) until after the transplant occurs, use 81267 plus 81265 and 81266 if necessary.

National Government Services would not expect to see a claim for 81265 pre-transplant and an additional 81265 and 81267 post-transplant or a claim for CPT codes 81265 pre-transplant and an additional claim for 81268.

Note: Although the initial chimerism testing, CPT code 81265, for engraftment is usually limited to once in a lifetime, National Government Services recognizes special circumstances may require an additional service and will consider approval on a case-by-case basis through the appeal process.

**CPT Code 81270**
JAK2 V617F genotyping is considered medically necessary in the initial diagnostic work-up of BCR-ABL negative, JAK2-negative adults with clinical, laboratory, or pathological findings suggesting polycythemia vera (PV), essential thrombocythemia (ET) or primary myelofibrosis (PMF). JAK2 (exons 12 and 13) is medically necessary in JAK2 V617F negative individuals for whom PV is a strong consideration.

**CPT Codes 81272, 81273**
CPT Code 81272 KIT (v-kit Hardy-Zuckerman 4 feline sarcoma viral oncogene homolog) (eg, gastrointestinal stromal tumor [GIST], acute myeloid leukemia, melanoma), gene analysis, targeted sequence analysis (eg, exons 8, 11, 13, 17, 18) is considered medically necessary in patients who have GIST, acute myeloid leukemia (AML) or melanoma to guide therapeutic decision making.

CPT Code 81273 KIT (v-kit Hardy-Zuckerman 4 feline sarcoma viral oncogene homolog) (eg, mastocytosis), gene analysis, D816 variant(s) is considered medically necessary in patients who have mastocytosis to guide therapeutic decision making.

**CPT Code 81275**
KRAS gene analysis, variants in codons 12 and 13, is considered medically necessary in patients with colorectal cancer or non-small cell lung cancer when needed to determine if a Medicare covered therapy is a reasonable option given the individual's specific clinical presentation.

**CPT Code 81276**
KRAS (Kirsten rat sarcoma viral oncogene homolog) (e.g., carcinoma) gene analysis; additional variant(s) (e.g., codon 61, codon 146) is considered medically necessary in patients with colorectal cancer or non-small cell lung cancer when needed to determine if a Medicare covered therapy is a reasonable option given the individual's specific clinical presentation.

**CPT Code 81287**
MGMT (O-6-methylguanine-DNA methyltransferase) (e.g., glioblastoma multiforme), methylation analysis) is considered medically necessary in patients with malignant brain neoplasm to guide therapeutic decision making.

**CPT Code 81291**
MTHFR (5,10-methyenetetrahydrofolate reductase) (e.g. hereditary hypercoaguability), gene analysis, common variants(e.g., EG, 677T, 1298C) is not considered to be clinically efficacious; therefore, testing is not medically necessary.

**CPT Code 81301**
Microsatellite instability analysis (e.g., hereditary non-polyposis colorectal cancer, Lynch syndrome) of markers for mismatch repair deficiency (e.g. BAT25, BAT26), includes comparison of neoplastic and normal tissue and is considered medically necessary in individuals who have colorectal cancer (CRC) diagnosed at less than or equal to 70 years of age, and those greater than 70 years who meet the revised Bethesda Lynch Syndrome (LS) guidelines to guide therapeutic decision-making.

Despite the high penetrance of CRC and endometrial cancer and recommendations of consideration for screening unaffected first-degree relatives following diagnosis of an LS proband, testing of genetic carriers who are unaffected with a Lynch- related cancer is not a Medicare benefit, and is statutorily excluded from coverage.

**CPT Code 81310**
NPM1 (nucleophosmin) is considered medically necessary in patients with acute myeloid leukemia (AML) to guide therapeutic decision making.

**CPT Code 81311**
NRAS (neuroblastoma RAS viral [v-ras] oncogene homolog) (e.g., colorectal carcinoma), gene analysis, variants in exon 2 (e.g., codons 12 and 13) and exon 3 (e.g., codon 61) is considered medically necessary in patients with colorectal cancer when needed to determine if a Medicare covered therapy is a reasonable option given the individual's specific clinical presentation.

**CPT Code 81313**
PCA3 testing is considered medically necessary in patients ONLY when all biopsies in previous encounter(s) are negative for prostatic cancer, the subsequent prostate specific antigen (PSA) is rising, and when the patient or physician wants to avoid repeat biopsy ("watchful waiting").

When the physician plans to biopsy the prostate, NGS will consider a PCA3 test as not medically necessary, and thus, not a covered Medicare benefit. NGS considers all other indications for PCA3 not reasonable and necessary.

Medical record documentation must indicate the rationale to perform a PCA3 assay.

**CPT Code 81314**
PDGFRA (platelet-derived growth factor receptor, alpha polypeptide) (e.g., gastrointestinal stromal tumor [GIST]), gene analysis, targeted sequence analysis (eg, exons 12, 18) is considered medically necessary in patients with PDGFRA-associated chronic eosinophilic leukemia or GIST caused by mutations in the PDGFRA gene to guide therapeutic decision making.

**CPT Codes 81315, 81316**
PML/RARALPHA, (T(15;17)), (PROMYELOCYTIC LEUKEMIA/RETINOIC ACID RECEPTOR ALPHA) (EG, PROMYELOCYTIC LEUKEMIA) TRANSLOCATION ANALYSIS; COMMON BREAKPOINTS (EG, INTRON 3 AND INTRON 6), QUALITATIVE OR QUANTITATIVE is considered medically necessary in patients with promyelocytic leukemia.

**CPT code 81332**
SERPINA1 (serpin peptidase inhibitor, clade A, alpha-1- antiproteinase, antitrypsin, member 1) (e.g., antitrypsin deficiency), gene analysis, common variants (e.g. *S and *Z) is considered medically necessary for patients who have antitrypsin deficiency to guide therapeutic decision-making.

**CPT Codes 81340, 81341, 81342**
TRB@ (T CELL antigen receptor, BETA) (e.g., leukemia and lymphoma), gene rearrangement analysis to detect abnormal cloning population(s); using amplification methodology is considered necessary to guide therapeutic decision-making for individuals with acute lymphoid leukemia, aplastic anemia, and T cell prolymphocytic leukemia.

TRG@ (T CELL antigen receptor, GAMMA ) (e.g., leukemia and lymphoma), gene rearrangement analysis , evaluation to detect abnormal cloning population(s) are considered medically necessary to guide therapeutic decision-making for individuals with acute lymphoid leukemia, aplastic anemia, and T cell prolymphocytic leukemia and mastocytosis.

**CPT Codes 81370- 81383**
HLA Class I or II typing is considered medically necessary when one of the following indications is met:

- Transplantation:
    - Standard of care determination of HLA matching for solid organ transplant (donor/recipient). – Solid organ transplant registries include both serological HLA testing (e.g., crossmatch) and genomic molecular DNA typing. Family members, or unrelated living donors or cadaveric donors who donate bone marrow or a solid organ are HLA tested pre-transplant to determine compatibility with the potential recipients.
    - Standard of care determination of HLA matching for solid organ transplant (donor/recipient). – Solid organ transplant registries include both serological HLA testing (e.g., crossmatch) and genomic molecular DNA typing. Family members, or unrelated living donors or cadaveric donors who donate bone marrow or a solid organ are HLA tested pre-transplant to determine compatibility with the potential recipients.
    - Standard of care identification of determination of HLA matching for hematopoietic stem cell/bone marrow transplantation -allele-level typing will provide clinical guidance for the HLA-A,B,C Class I and DRB1, DQB1,DPB1, and DQA1 Class II loci in the average transplant program because it is well established that mismatches at certain HLA loci between donor-recipients are closely linked to the risk of graft versus host disease. Potential marrow donors may enroll with a national registry such as the United States National Marrow Donor Program or the Canadian Blood Services registry.
- Disease Association:

- Standard of care testing to diagnose certain HLA related diseases/conditions when the testing is supported by the clinical literature and is informative for the direct management of a patient bearing a certain allele(s). It is not expected that more than one test would be required in a given beneficiary's lifetime. Possible covered indications when standard laboratory testing (tissue typing) not adequate:

    - HLA-B*27 for the diagnosis of certain cases of symptomatic patients with presumed ankylosing spondylitis or related inflammatory disease. HLA-B*27 is covered for ankylosing spondylitis in cases where other methods of diagnosis would not be appropriate or have yielded inconclusive results (NCD 190.1).

    - In the work-up of certain patients with an unclear diagnosis of celiac disease and gluten hypersensitivity usually related to ambiguous standard laboratory results and/or inconsistent biopsy results (e.g., HLA-DQ2 by HLA-DQB1*02 and of DQ8 by HLA-DQB1*0302).

- Pharmacogenetics:

    - Standard of care testing to diagnose certain HLA related drug hypersensitivity reactions when the testing is supported by the clinical literature and is informative for the direct management of a patient bearing a certain allele(s) associated to fatal skin drug reactions (Stevens-Johnson syndrome and toxic epidermal necrolysis). It is not expected that more than one test would be required in a given beneficiary's lifetime. Possible covered indications:

        - HLA –B*5701 when testing performed prior to the initiation of an abacavir-containing regime in the treatment of HIV Infection.

        - HLA-B*1502 when genotyping may be useful for risk stratification when the testing is performed prior to the initiation of carbamazepine therapy in the treatment of patients at high risk of having this allele. HLA-B*1502 occurs almost exclusively in patients with ancestry across broad areas of Asia, including South Asian Indians.

- Identification of HLA compatible platelets for transfusion when standard typing is not adequate.

**CPT Code 81401**
IGH@BCL2 (t(14:18)) (e.g., follicular lymphoma), translocation analysis; single breakpoint (e.g., major breakpoint region [MBR] or minor cluster region [mcr]), qualitative or quantitative is considered medical necessary for patients who have non- Hodgkin's lymphoma to guide therapeutic decision-making.

**CPT Code 81402**
MPL (myeloproliferative leukemia virus oncogene, thrombopoietin receptor, TPOR) (eg, myeloproliferative disorder), common variants (eg, W515A, W515K, W515L, W515R) is considered medically necessary in the initial work-up of BCR-ABL negative, JAK2 negative, and CALR negative adults with clinical, laboratory, or pathological findings suggesting thrombocytosis, essential thrombocythemia (ET), or primary myelofibrosis (PMF).

**CPT Code 81403**
MPL (myeloproliferative leukemia virus oncogene, thrombopoietin receptor, TPOR) (eg, myeloproliferative disorder), exon 10 sequence is considered medically necessary in the initial work-up of BCR-ABL negative, JAK2 negative, and CALR negative adults with clinical, laboratory, or pathological findings suggesting thrombocytosis, essential thrombocythemia (ET), or primary myelofibrosis (PMF).

**CPT Code 81403**
JAK2 (Janus kinase 2) (eg, myeloproliferative disorder), exon 12 sequence and exon 13 sequence is considered medically necessary in the initial work-up of BCR-ABL and JAK2 (V617F variant) negative adults with clinical, laboratory, or pathological findings suggesting polycythemia vera.

**CPT code 81404, and 81405**
RET (ret-proto-oncogene) is considered medically necessary in patients with medullary CA of thyroid, multiple endocrine neoplasia, pheochromocytoma, and parathyroid tumors) to guide therapeutic decision making.

**CPT Code 81406**
ATP7B is considered medically necessary in patients with symptoms of Wilson's disease to guide therapeutic decision making.

**CPT Code 81445**
Targeted genomic sequence analysis panel, solid organ neoplasm, DNA analysis, and RNA analysis when performed, 5-50 genes (EG, ALK, BRAF, CDKN2A, EGFR, ERBB2, KIT, KRAS, NRAS, MET, PDGFRA, PDGFRB, PGR, PIK3CA, PTEN, RET), interrogation for sequence variants and copy number variants or rearrangements, if performed is considered not medically necessary except when used to guide treatment decision making in individuals with non-small cell lung cancer (please refer to LCD L36376).

**CPT code 81479**
ROS proto-oncogene 1, receptor tyrosine kinase, is considered medically necessary in patients with non-small cell lung cancer when needed to determine if a Medicare covered therapy is a reasonable option given the individuals specific clinical presentation.

MET proto-oncogene, receptor tyrosine kinase, is considered medically necessary in patients with non-small cell lung cancer when needed to determine if a Medicare covered therapy is a reasonable option given the individuals specific clinical presentation.

**CPT Code 81519**
Oncology (breast), mRNA, gene expression profiling by real-time RT-PCR of 21 genes, utilizing formalin-fixed paraffin embedded tissue, algorithm reported as recurrence score is considered medically necessary to guide therapeutic decision-making in patients with the following findings:

- estrogen-receptor positive, node-negative carcinoma of the breast
- estrogen-receptor positive micrometastases of carcinoma of the breast, and
- estrogen-receptor positive breast carcinoma with 1-3 positive nodes.

**CPT Code 81595**
Cardiology (heart transplant), mRNA, gene expression profiling by real-time quantitative PCR of 20 genes (11 content and 9 housekeeping), utilizing subtraction of peripheral blood, algorithm reported as rejection risk score is considered medically necessary for heart transplant patients to guide therapeutic decision-making.

**CPT Code 0008M**
Prosigna® Breast Cancer Prognostic Gene Signature Assay is considered medically necessary in patients who have undergone surgery in conjunction with locoregional treatment consistent with standard of care, either as:

- A prognostic indicator for distant recurrence-free survival at 10 years in post- menopausal women with Hormone Receptor-Positive (HR+), lymph node-negative, Stage I or II breast cancer to be treated with adjuvant endocrine therapy alone, when used in conjunction with other clinicopathological factors.

- A prognostic indicator for distant recurrence-free survival at 10 years in post- menopausal women with Hormone Receptor-Positive (HR+), lymph node-positive (1-3 positive nodes}, Stage II breast cancer to be treated with adjuvant endocrine therapy alone, when used in conjunction with other clinicopathological factors. The device is not intended for patients with 4 or more positive nodes

**COVERED MOLECULAR PATHOLOGY PROCEDURES**
Limited coverage may be provided for specific genes reported below (refer to CPT/HCPCS code section (Group 1). Any genetic test, not listed, will require individual review.

81400 ACE
81400 F13B
81400 F5
81400 F7
81400 FGB
81400 Human Platelet Antigen ANTIGEN 1(HPA-1)
81400 Human Platelet Antigen ANTIGEN 15(HPA-15)

81400 Human Platelet Antigen ANTIGEN 2(HPA-2)
81400 Human Platelet Antigen ANTIGEN 3(HPA-3)
81400 Human Platelet Antigen ANTIGEN 4(HPA-4)
81400 Human Platelet Antigen ANTIGEN 5(HPA-5)
81400 Human Platelet Antigen ANTIGEN 6(HPA-6w)
81400 Human platelet antigen 9 genotyping (HPA-9w),
81401 CCND1/IGH
81401 CBFB-MYH11
81401 E2A/PBX1
81401 EML4-ALK
81401 ETV6-RUNX1
81401 EWSR1/ERG
81401 EWSR1/FLI1
81401 EWSR1/WT1
81401 F11coagulation factor XI
81401 FIP1L1-PDGFR
81401 FOXO1/PAX3
81401 FOXO1/PAX7
81401 MUTYH (mutY homolog [E.coli])
81401 NPM/ALK
81401 PAX8/PPARG
81401 RUNX1/RUNX1T1
81401 TPMT (thiopurine S-methyltransferase)
81401 TYMS (thymidylate synthetase)
81403 F8 (coagulation factor VIII)
81403 VHL (von Hippel-Lindau tumor suppressor)
81404 CDKN2A (cyclin-dependent kinase inhibitor 2A)
81404 PRSS1 (protease, serine, 1 [trypsin 1])
81404 VHL (von Hippel-Lindau tumor suppressor)
81405 MEN1 (multiple endocrine neoplasia I)
81406 ATP7B (ATPase, Cu++ transporting, beta polypeptide)

**MOLECULAR PATHOLOGY PROCEDURES THAT REQUIRE INDIVIDUAL REVIEW**
Please refer to CPT/HCPCS Code section (Group 2) for specific tests.
Any genetic test reported with a CPT code, not listed above or below, is subject to individual review.

**NON-COVERED MOLECULAR PATHOLOGY PROCEDURES**
Please refer to CPT/HCPCS Code section (Group 3) for specific tests. Also, please note that this list does not include non-covered genetic tests specifically mentioned above (e.g. CPT 81240 and 81241)

The following individual genetic tests are unlikely to impact therapeutic decision-making, directly impact treatment, outcome and/or clinical management in the care of the beneficiary and will be denied as not medically necessary (Please note that this list of non-covered genes is not exhaustive, and the fact that a specific gene is not mentioned does not mean it is covered. In addition, many genes have several names that are used. The most common names have been used in this policy):

81400 ABCC8
81400 ACADM
81400 AGTR1
81400 CCR5
81400 CLRN1
81400 DPYD
81400 DYT1 (TOR1A)
81400 FGFR3
81400 IL28B
81400 IVD
81400 SMN1
81400 TOR1A
81401 ADRB2
81401 APOE
81401 AR (androgen receptor)
81401 ATN1
81401 CFH/ARMS2
81401 CYP3A4
81401 CYP3A5
81401 DEK/NUP214
81401 DMPK (dystrophia myotonica-protein kinase)

81401 FGFR3
81401 GALT (galactose-1-phosphate uridylyltransferase)
81401 H19
81401 HTT (huntingtin)
81401 KCNQ10T1 (KCNQ1 overlapping transcript 1)
81401 MEG3/DLK1
81401 MLL/AFF
81401 MT-ATP6
81401 MT-ND4, MT-ND6
81401 MT-ND5 mitochondrially encoded tRNA leucine 1 [UUA/G] mitochondrially encoded NADH dehydrogenase 5)
81401 MT-RNR1 (mitochondrially encoded 12S RNA)
81401 MT-TK (mitochondrially encoded tRNA lysine)
81401 MT-TL1
81401 MT-TS1
81401 PRSS1 (protease, serine, 1 [trypsin 1])
81401 SEPT9 (Septin 9)
81401 SMN1/SMN2 (survival of motor neuron 1, telomeric/survival of motor neuron 2, centromeric)
81402 CYP21A2
81402 Chromosome 18q-
81402 MEFV (Mediterranean fever) (eg, familial Mediterranean fever)
81402 TRD
81402 Uniparental disomy (UPD)
81403 ANG (angiogenin, ribonuclease, RNase A family, 5)
81403 FGFR3 (fibroblast growth factor receptor 3) one exon
81403 GJB1 (gap junction protein, beta 1) (eg, Charcot-Marie-Tooth X-linked), full gene sequence
81403 HRAS (v-Ha-ras Harvey rat sarcoma viral oncogene homolog Costello syndrome)
81403 MT-RNR1 (mitochondrially encoded 12S RNA)
81403 MT-TS1 (mitochondrially encoded tRNA serine 1)
81403 SMN1 (survival of motor neuron 1, telomeric)
81404 ACADS (acyl-CoA dehydrogenase)
81404 AQP2 (aquaporin 2 [collecting duct])
81404 ARX (aristaless related homeobox)
81404 BTD (biotinidase)
81404 CAV3 (caveolin 3) (eg, CAV3-related distal myopathy, limb-girdle muscular dystrophy type 1C), full gene sequence
81404 CLRN1 (clarin 1)
81404 CYP1B1 (cytochrome P450, family 1, subfamily B, polypeptide 1)
81404 DMPK (dystrophia myotonica-protein kinase (DM gene and DM1)
81404 EGR2 (early growth response 2) (eg, Charcot-Marie-Tooth)
81404 FGFR2 (fibroblast growth factor receptor 2) (2 EXONS)
81404 FGFR3 (fibroblast growth factor receptor 3) (4 EXONS)
81404 FKRP (Fukutin related protein)
81404 FOXG1 (forkhead box G1)
81404 FSHMD1A (facioscapulohumeral muscular dystrophy 1A)
81404 FSHMD1A (facioscapulohumeral muscular dystrophy 1A) (eg
81404 FXN (frataxin)
81404 HBA1/HBA2 (alpha globin 1 and alpha globin 2)
81404 HBB (hemoglobin, beta, beta-globin)
81404 HNF1B (HNF1 homeobox B)
81404 HRAS (v-Ha-ras Harvey rat sarcoma viral oncogene homolog)
81404 KCNJ10 (potassium inwardly-rectifying channel, subfamily J, member 10)
81404 MEN1 (multiple endocrine neoplasia I)
81404 SLC25A4 (solute carrier family 25 [mitochondrial carrier; adenine nucleotide translocation]
81404 TP53 (tumor protein 53
81404 VWF (von Willebrand factor)
81405 CASR (CAR, EIG8, extracellular calcium-sensing receptor, FHH, FIH, GPRC2A, HHC, HHC1, NSHPT, PCAR1)
81405 CYP21A2 (cytochrome P450, family 21, subfamily A, polypeptide2)
81405 MPZ (myelin protein zero)
81406 ACADVL (acyl-CoA dehydrogenase, very long chain)
81406 CBS (cystathionine-beta-synthase)
81406 CDKL5 (cyclin-dependent kinase-like 5)
81406 DLAT (dihydrolipoamide S-acetyltransferase)
81406 DLD (dihydrolipoamide dehydrogenase)
81406 F8 (coagulation factor VIII)
81406 GALT (galactose-1-phosphate uridylyltransferase)
81406 HADHA (hydroxyacyl-CoA dehydrogenase/3-ketoacyl-CoA thiolase/enoyl-CoA hydratase [trifunctional protein] alpha subunit)

81406 HEXA (hexosaminidase A, alpha polypeptide)
81406 LMNA (lamin A/C)
81406 MUTYH (mutY homolog [E. coli])
81406 NF2 (neurofibromin 2 [merlin])
81406 NSD1 (nuclear receptor binding SET domain protein 1)
81406 PAH (phenylalanine hydroxylase)
81406 PAX2 (paired box 2)
81406 PDHA1 (pyruvate dehydrogenase [lipoamide] alpha1)
81406 POLG (polymerase [DNA directed], gamma)
81406 PRKAG2 (protein kinase, AMP-activated, gamma 2 non-catalytic subunit)
81406 PTPN11 (protein tyrosine phosphatase, non-receptor type 11)
81406 RET (ret-proto-oncogene) full gene sequence
81406 SLC9A6 (solute carrier family 9 [sodium/hydrogen exchanger] member 6)
81406 SOS1 (son of sevenless homolog 1)
81406 TAZ (tafazzin)
81406 TSC1 (tuberous sclerosis 1)
81406 TSC2 (tuberous sclerosis 2)
81406 UBE3A (ubiquitin protein ligase)
81407 Level 8 Molecular Pathology Procedures
81407 F8 (coagulation factor VIII)
81408 Level 9 Molecular Pathology Procedures
81479 SLCO1B1-Statin Myopathy
81479 PIK3C, PI3Ks, PI(3)Ks, PI-3Ks
81479 AKT1
81479 MEK1
81479 VEGFR2 (CD309, FLK1, VEGFR)
81479 LPA intron 25 genotype
81479 KIF6
81479 SPG4
81479 C9orf72
81479 MLH1
81479 AIRE (APSI)
81479 SCA1
81479 SDA2
81479 HAX1 (HAX1_HUMAN, HCLS1- associated protein X-1, HCLSBP1, HS1-associating protein X-1, HS1 binding protein, HS1-binding protein 1, HS1BP1, HSP1BP-1)

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# Coding Information

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 policy does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy 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 policy, 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 policy should be assumed to apply equally to all 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 policy 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 policy should be assumed to apply equally to all Revenue Codes.

Revenue codes only apply to providers who bill these services to the Part A MAC. Revenue codes do not apply to physicians, other professionals and suppliers who bill these services to the Part B MAC.

Please note that not all revenue codes apply to every type of bill code. Providers are encouraged to refer to the FISS revenue code file for allowable bill types. Similarly, not all revenue codes apply to each CPT/HCPCS code. Providers are encouraged to refer to the FISS HCPCS file for allowable revenue codes.

030X Laboratory - General Classification
031X Laboratory Pathology - General Classification

CPT/HCPCS Codes
**Group 1 Paragraph: COVERED MOLECULAR PATHOLOGY PROCEDURES**

Limited coverage may be provided for the genetic tests, submitted under the following CPT codes:

Note: Please refer to the Indications and Limitations of Coverage section and the ICD-10-CM diagnosis to CPT procedure groupings. Not all procedure codes have related diagnosis codes listed.

**Group 1 Codes:**

| | |
|---|---|
| 0008M | ONCOLOGY (BREAST), MRNA ANALYSIS OF 58 GENES USING HYBRID CAPTURE, ON FORMALIN-FIXED PARAFFIN-EMBEDDED (FFPE) TISSUE, PROGNOSTIC ALGORITHM REPORTED AS A RISK SCORE |
| 81162 | BRCA1, BRCA2 (BREAST CANCER 1 AND 2) (EG, HEREDITARY BREAST AND OVARIAN CANCER) GENE ANALYSIS; FULL SEQUENCE ANALYSIS AND FULL DUPLICATION/DELETION ANALYSIS |
| 81170 | ABL1 (ABL PROTO-ONCOGENE 1, NON-RECEPTOR TYROSINE KINASE) (EG, ACQUIRED IMATINIB TYROSINE KINASE INHIBITOR RESISTANCE), GENE ANALYSIS, VARIANTS IN THE KINASE DOMAIN |
| 81206 | BCR/ABL1 (T(9;22)) (EG, CHRONIC MYELOGENOUS LEUKEMIA) TRANSLOCATION ANALYSIS; MAJOR BREAKPOINT, QUALITATIVE OR QUANTITATIVE |
| 81207 | BCR/ABL1 (T(9;22)) (EG, CHRONIC MYELOGENOUS LEUKEMIA) TRANSLOCATION ANALYSIS; MINOR BREAKPOINT, QUALITATIVE OR QUANTITATIVE |
| 81208 | BCR/ABL1 (T(9;22)) (EG, CHRONIC MYELOGENOUS LEUKEMIA) TRANSLOCATION ANALYSIS; OTHER BREAKPOINT, QUALITATIVE OR QUANTITATIVE |
| 81209 | BLM (BLOOM SYNDROME, RECQ HELICASE-LIKE) (EG, BLOOM SYNDROME) GENE ANALYSIS, 2281DEL6INS7 VARIANT |
| 81210 | BRAF (B-RAF PROTO-ONCOGENE, SERINE/THREONINE KINASE) (EG, COLON CANCER, MELANOMA), GENE ANALYSIS, V600 VARIANT(S) |
| 81211 | BRCA1, BRCA2 (BREAST CANCER 1 AND 2) (EG, HEREDITARY BREAST AND OVARIAN CANCER) GENE ANALYSIS; FULL SEQUENCE ANALYSIS AND COMMON DUPLICATION/DELETION VARIANTS IN BRCA1 (IE, 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) (EG, HEREDITARY BREAST AND OVARIAN CANCER) GENE ANALYSIS; 185DELAG, 5385INSC, 6174DELT VARIANTS |
| 81213 | BRCA1, BRCA2 (BREAST CANCER 1 AND 2) (EG, HEREDITARY BREAST AND OVARIAN CANCER) GENE ANALYSIS; UNCOMMON DUPLICATION/DELETION VARIANTS |
| 81214 | BRCA1 (BREAST CANCER 1) (EG, HEREDITARY BREAST AND OVARIAN CANCER) GENE ANALYSIS; FULL SEQUENCE ANALYSIS AND COMMON DUPLICATION/DELETION VARIANTS (IE, 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) (EG, HEREDITARY BREAST AND OVARIAN CANCER) GENE ANALYSIS; KNOWN FAMILIAL VARIANT |
| 81216 | BRCA2 (BREAST CANCER 2) (EG, HEREDITARY BREAST AND OVARIAN CANCER) GENE ANALYSIS; FULL SEQUENCE ANALYSIS |
| 81217 | BRCA2 (BREAST CANCER 2) (EG, HEREDITARY BREAST AND OVARIAN CANCER) GENE ANALYSIS; KNOWN FAMILIAL VARIANT |
| 81218 | CEBPA (CCAAT/ENHANCER BINDING PROTEIN [C/EBP], ALPHA) (EG, ACUTE MYELOID LEUKEMIA), GENE ANALYSIS, FULL GENE SEQUENCE |
| 81219 | CALR (CALRETICULIN) (EG, MYELOPROLIFERATIVE DISORDERS), GENE ANALYSIS, COMMON VARIANTS IN EXON 9 |
| 81220 | CFTR (CYSTIC FIBROSIS TRANSMEMBRANE CONDUCTANCE REGULATOR) (EG, CYSTIC FIBROSIS) GENE ANALYSIS; COMMON VARIANTS (EG, ACMG/ACOG GUIDELINES) |
| 81221 | |

CFTR (CYSTIC FIBROSIS TRANSMEMBRANE CONDUCTANCE REGULATOR) (EG, CYSTIC FIBROSIS) GENE ANALYSIS; KNOWN FAMILIAL VARIANTS

81222 CFTR (CYSTIC FIBROSIS TRANSMEMBRANE CONDUCTANCE REGULATOR) (EG, CYSTIC FIBROSIS) GENE ANALYSIS; DUPLICATION/DELETION VARIANTS

81223 CFTR (CYSTIC FIBROSIS TRANSMEMBRANE CONDUCTANCE REGULATOR) (EG, CYSTIC FIBROSIS) GENE ANALYSIS; FULL GENE SEQUENCE

81224 CFTR (CYSTIC FIBROSIS TRANSMEMBRANE CONDUCTANCE REGULATOR) (EG, CYSTIC FIBROSIS) GENE ANALYSIS; INTRON 8 POLY-T ANALYSIS (EG, MALE INFERTILITY)

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)

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)

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)

81256 HFE (HEMOCHROMATOSIS) (EG, HEREDITARY HEMOCHROMATOSIS) GENE ANALYSIS, COMMON VARIANTS (EG, C282Y, H63D)

81261 IGH@ (IMMUNOGLOBULIN HEAVY CHAIN LOCUS) (EG, LEUKEMIAS AND LYMPHOMAS, B-CELL), GENE REARRANGEMENT ANALYSIS TO DETECT ABNORMAL CLONAL POPULATION(S); AMPLIFIED METHODOLOGY (EG, POLYMERASE CHAIN REACTION)

81262 IGH@ (IMMUNOGLOBULIN HEAVY CHAIN LOCUS) (EG, LEUKEMIAS AND LYMPHOMAS, B-CELL), GENE REARRANGEMENT ANALYSIS TO DETECT ABNORMAL CLONAL POPULATION(S); DIRECT PROBE METHODOLOGY (EG, SOUTHERN BLOT)

81263 IGH@ (IMMUNOGLOBULIN HEAVY CHAIN LOCUS) (EG, LEUKEMIA AND LYMPHOMA, B-CELL), VARIABLE REGION SOMATIC MUTATION ANALYSIS

81264 IGK@ (IMMUNOGLOBULIN KAPPA LIGHT CHAIN LOCUS) (EG, 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 (EG, PRE-TRANSPLANT RECIPIENT AND DONOR GERMLINE TESTING, POST-TRANSPLANT NON-HEMATOPOIETIC RECIPIENT GERMLINE [EG, 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 (EG, 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 (EG, HEMATOPOIETIC STEM CELL), INCLUDES COMPARISON TO PREVIOUSLY PERFORMED BASELINE ANALYSES; WITHOUT CELL SELECTION

81268 CHIMERISM (ENGRAFTMENT) ANALYSIS, POST TRANSPLANTATION SPECIMEN (EG, HEMATOPOIETIC STEM CELL), INCLUDES COMPARISON TO PREVIOUSLY PERFORMED BASELINE ANALYSES; WITH CELL SELECTION (EG, CD3, CD33), EACH CELL TYPE

81270 JAK2 (JANUS KINASE 2) (EG, MYELOPROLIFERATIVE DISORDER) GENE ANALYSIS, P.VAL617PHE (V617F) VARIANT

81272 KIT (V-KIT HARDY-ZUCKERMAN 4 FELINE SARCOMA VIRAL ONCOGENE HOMOLOG) (EG, GASTROINTESTINAL STROMAL TUMOR [GIST], ACUTE MYELOID LEUKEMIA, MELANOMA), GENE ANALYSIS, TARGETED SEQUENCE ANALYSIS (EG, EXONS 8, 11, 13, 17, 18)

81273 KIT (V-KIT HARDY-ZUCKERMAN 4 FELINE SARCOMA VIRAL ONCOGENE HOMOLOG) (EG, MASTOCYTOSIS), GENE ANALYSIS, D816 VARIANT(S)

81275 KRAS (KIRSTEN RAT SARCOMA VIRAL ONCOGENE HOMOLOG) (EG, CARCINOMA) GENE ANALYSIS; VARIANTS IN EXON 2 (EG, CODONS 12 AND 13)

81276 KRAS (KIRSTEN RAT SARCOMA VIRAL ONCOGENE HOMOLOG) (EG, CARCINOMA) GENE ANALYSIS; ADDITIONAL VARIANT(S) (EG, CODON 61, CODON 146)

81287 MGMT (O-6-METHYLGUANINE-DNA METHYLTRANSFERASE) (EG, GLIOBLASTOMA MULTIFORME), METHYLATION ANALYSIS

81301 MICROSATELLITE INSTABILITY ANALYSIS (EG, 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

81310 NPM1 (NUCLEOPHOSMIN) (EG, ACUTE MYELOID LEUKEMIA) GENE ANALYSIS, EXON 12 VARIANTS

81311 NRAS (NEUROBLASTOMA RAS VIRAL [V-RAS] ONCOGENE HOMOLOG) (EG, COLORECTAL CARCINOMA), GENE ANALYSIS, VARIANTS IN EXON 2 (EG, CODONS 12 AND 13) AND EXON 3 (EG, CODON 61)

81313 PCA3/KLK3 (PROSTATE CANCER ANTIGEN 3 [NON-PROTEIN CODING]/KALLIKREIN-RELATED PEPTIDASE 3 [PROSTATE SPECIFIC ANTIGEN]) RATIO (EG, PROSTATE CANCER)

81314 PDGFRA (PLATELET-DERIVED GROWTH FACTOR RECEPTOR, ALPHA POLYPEPTIDE) (EG, GASTROINTESTINAL STROMAL TUMOR [GIST]), GENE ANALYSIS, TARGETED SEQUENCE ANALYSIS (EG, EXONS 12, 18)

81315 PML/RARALPHA, (T(15;17)), (PROMYELOCYTIC LEUKEMIA/RETINOIC ACID RECEPTOR ALPHA) (EG, PROMYELOCYTIC LEUKEMIA) TRANSLOCATION ANALYSIS; COMMON BREAKPOINTS (EG, INTRON 3 AND INTRON 6), QUALITATIVE OR QUANTITATIVE

81316 PML/RARALPHA, (T(15;17)), (PROMYELOCYTIC LEUKEMIA/RETINOIC ACID RECEPTOR ALPHA) (EG, PROMYELOCYTIC LEUKEMIA) TRANSLOCATION ANALYSIS; SINGLE BREAKPOINT (EG, INTRON 3, INTRON 6 OR EXON 6), QUALITATIVE OR QUANTITATIVE

81332 SERPINA1 (SERPIN PEPTIDASE INHIBITOR, CLADE A, ALPHA-1 ANTIPROTEINASE, ANTITRYPSIN, MEMBER 1) (EG, ALPHA-1-ANTITRYPSIN DEFICIENCY), GENE ANALYSIS, COMMON VARIANTS (EG, *S AND *Z)

81340 TRB@ (T CELL ANTIGEN RECEPTOR, BETA) (EG, LEUKEMIA AND LYMPHOMA), GENE REARRANGEMENT ANALYSIS TO DETECT ABNORMAL CLONAL POPULATION(S); USING AMPLIFICATION METHODOLOGY (EG, POLYMERASE CHAIN REACTION)

81341 TRB@ (T CELL ANTIGEN RECEPTOR, BETA) (EG, LEUKEMIA AND LYMPHOMA), GENE REARRANGEMENT ANALYSIS TO DETECT ABNORMAL CLONAL POPULATION(S); USING DIRECT PROBE METHODOLOGY (EG, SOUTHERN BLOT)

81342 TRG@ (T CELL ANTIGEN RECEPTOR, GAMMA) (EG, LEUKEMIA AND LYMPHOMA), GENE REARRANGEMENT ANALYSIS, EVALUATION TO DETECT ABNORMAL CLONAL POPULATION(S)

81370 HLA CLASS I AND II TYPING, LOW RESOLUTION (EG, ANTIGEN EQUIVALENTS); HLA-A, -B, -C, -DRB1/3/4/5, AND -DQB1

81371 HLA CLASS I AND II TYPING, LOW RESOLUTION (EG, ANTIGEN EQUIVALENTS); HLA-A, -B, AND -DRB1 (EG, VERIFICATION TYPING)

81372 HLA CLASS I TYPING, LOW RESOLUTION (EG, ANTIGEN EQUIVALENTS); COMPLETE (IE, HLA-A, -B, AND -C)

81373 HLA CLASS I TYPING, LOW RESOLUTION (EG, ANTIGEN EQUIVALENTS); ONE LOCUS (EG, HLA-A, -B, OR -C), EACH

81374 HLA CLASS I TYPING, LOW RESOLUTION (EG, ANTIGEN EQUIVALENTS); ONE ANTIGEN EQUIVALENT (EG, B*27), EACH

81375 HLA CLASS II TYPING, LOW RESOLUTION (EG, ANTIGEN EQUIVALENTS); HLA-DRB1/3/4/5 AND -DQB1

81376 HLA CLASS II TYPING, LOW RESOLUTION (EG, ANTIGEN EQUIVALENTS); ONE LOCUS (EG, HLA-DRB1, -DRB3/4/5, -DQB1, -DQA1, -DPB1, OR -DPA1), EACH

81377 HLA CLASS II TYPING, LOW RESOLUTION (EG, ANTIGEN EQUIVALENTS); ONE ANTIGEN EQUIVALENT, EACH

81378 HLA CLASS I AND II TYPING, HIGH RESOLUTION (IE, ALLELES OR ALLELE GROUPS), HLA-A, -B, -C, AND -DRB1

81379 HLA CLASS I TYPING, HIGH RESOLUTION (IE, ALLELES OR ALLELE GROUPS); COMPLETE (IE, HLA-A, -B, AND -C)

81380 HLA CLASS I TYPING, HIGH RESOLUTION (IE, ALLELES OR ALLELE GROUPS); ONE LOCUS (EG, HLA-A, -B, OR -C), EACH

81381 HLA CLASS I TYPING, HIGH RESOLUTION (IE, ALLELES OR ALLELE GROUPS); ONE ALLELE OR ALLELE GROUP (EG, B*57:01P), EACH

81382 HLA CLASS II TYPING, HIGH RESOLUTION (IE, ALLELES OR ALLELE GROUPS); ONE LOCUS (EG, HLA-DRB1, -DRB3/4/5, -DQB1, -DQA1, -DPB1, OR -DPA1), EACH

81383 HLA CLASS II TYPING, HIGH RESOLUTION (IE, ALLELES OR ALLELE GROUPS); ONE ALLELE OR ALLELE GROUP (EG, HLA-DQB1*06:02P), EACH

81400 MOLECULAR PATHOLOGY PROCEDURE, LEVEL 1 (EG, IDENTIFICATION OF SINGLE GERMLINE VARIANT [EG, SNP] BY TECHNIQUES SUCH AS RESTRICTION ENZYME DIGESTION OR MELT CURVE ANALYSIS)

81401 MOLECULAR PATHOLOGY PROCEDURE, LEVEL 2 (EG, 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)

81403 MOLECULAR PATHOLOGY PROCEDURE, LEVEL 4 (EG, 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 (EG, 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)

81405 MOLECULAR PATHOLOGY PROCEDURE, LEVEL 6 (EG, ANALYSIS OF 6-10 EXONS BY DNA SEQUENCE ANALYSIS, MUTATION SCANNING OR DUPLICATION/DELETION VARIANTS OF 11-25 EXONS)

81406

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| | 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) |
| 81519 | ONCOLOGY (BREAST), MRNA, GENE EXPRESSION PROFILING BY REAL-TIME RT-PCR OF 21 GENES, UTILIZING FORMALIN-FIXED PARAFFIN EMBEDDED TISSUE, ALGORITHM REPORTED AS RECURRENCE SCORE |
| 81595 | CARDIOLOGY (HEART TRANSPLANT), MRNA, GENE EXPRESSION PROFILING BY REAL-TIME QUANTITATIVE PCR OF 20 GENES (11 CONTENT AND 9 HOUSEKEEPING), UTILIZING SUBFRACTION OF PERIPHERAL BLOOD, ALGORITHM REPORTED AS A REJECTION RISK SCORE |

**Group 2 Paragraph: MOLECULAR PATHOLOGY PROCEDURES THAT REQUIRE INDIVIDUAL REVIEW**

Coverage may be provided for the genetic tests submitted under the following CPT codes, if documentation supports medical necessity:

Note: Please refer to the Indications and Limitations of Coverage section and the ICD-10-CM diagnosis to CPT procedure groupings. Not all procedure codes have related diagnosis codes listed.

**Group 2 Codes:**

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| 81288 | MLH1 (MUTL HOMOLOG 1, COLON CANCER, NONPOLYPOSIS TYPE 2) (EG, HEREDITARY NON-POLYPOSIS COLORECTAL CANCER, LYNCH SYNDROME) GENE ANALYSIS; PROMOTER METHYLATION ANALYSIS |
| 81292 | MLH1 (MUTL HOMOLOG 1, COLON CANCER, NONPOLYPOSIS TYPE 2) (EG, HEREDITARY NON-POLYPOSIS COLORECTAL CANCER, LYNCH SYNDROME) GENE ANALYSIS; FULL SEQUENCE ANALYSIS |
| 81293 | MLH1 (MUTL HOMOLOG 1, COLON CANCER, NONPOLYPOSIS TYPE 2) (EG, HEREDITARY NON-POLYPOSIS COLORECTAL CANCER, LYNCH SYNDROME) GENE ANALYSIS; KNOWN FAMILIAL VARIANTS |
| 81294 | MLH1 (MUTL HOMOLOG 1, COLON CANCER, NONPOLYPOSIS TYPE 2) (EG, HEREDITARY NON-POLYPOSIS COLORECTAL CANCER, LYNCH SYNDROME) GENE ANALYSIS; DUPLICATION/DELETION VARIANTS |
| 81295 | MSH2 (MUTS HOMOLOG 2, COLON CANCER, NONPOLYPOSIS TYPE 1) (EG, HEREDITARY NON-POLYPOSIS COLORECTAL CANCER, LYNCH SYNDROME) GENE ANALYSIS; FULL SEQUENCE ANALYSIS |
| 81296 | MSH2 (MUTS HOMOLOG 2, COLON CANCER, NONPOLYPOSIS TYPE 1) (EG, HEREDITARY NON-POLYPOSIS COLORECTAL CANCER, LYNCH SYNDROME) GENE ANALYSIS; KNOWN FAMILIAL VARIANTS |
| 81297 | MSH2 (MUTS HOMOLOG 2, COLON CANCER, NONPOLYPOSIS TYPE 1) (EG, HEREDITARY NON-POLYPOSIS COLORECTAL CANCER, LYNCH SYNDROME) GENE ANALYSIS; DUPLICATION/DELETION VARIANTS |
| 81298 | MSH6 (MUTS HOMOLOG 6 [E. COLI]) (EG, HEREDITARY NON-POLYPOSIS COLORECTAL CANCER, LYNCH SYNDROME) GENE ANALYSIS; FULL SEQUENCE ANALYSIS |
| 81299 | MSH6 (MUTS HOMOLOG 6 [E. COLI]) (EG, HEREDITARY NON-POLYPOSIS COLORECTAL CANCER, LYNCH SYNDROME) GENE ANALYSIS; KNOWN FAMILIAL VARIANTS |
| 81300 | MSH6 (MUTS HOMOLOG 6 [E. COLI]) (EG, HEREDITARY NON-POLYPOSIS COLORECTAL CANCER, LYNCH SYNDROME) GENE ANALYSIS; DUPLICATION/DELETION VARIANTS |
| 81317 | PMS2 (POSTMEIOTIC SEGREGATION INCREASED 2 [S. CEREVISIAE]) (EG, HEREDITARY NON-POLYPOSIS COLORECTAL CANCER, LYNCH SYNDROME) GENE ANALYSIS; FULL SEQUENCE ANALYSIS |
| 81318 | PMS2 (POSTMEIOTIC SEGREGATION INCREASED 2 [S. CEREVISIAE]) (EG, HEREDITARY NON-POLYPOSIS COLORECTAL CANCER, LYNCH SYNDROME) GENE ANALYSIS; KNOWN FAMILIAL VARIANTS |
| 81319 | PMS2 (POSTMEIOTIC SEGREGATION INCREASED 2 [S. CEREVISIAE]) (EG, HEREDITARY NON-POLYPOSIS COLORECTAL CANCER, LYNCH SYNDROME) GENE ANALYSIS; DUPLICATION/DELETION VARIANTS |
| 81321 | PTEN (PHOSPHATASE AND TENSIN HOMOLOG) (EG, COWDEN SYNDROME, PTEN HAMARTOMA TUMOR SYNDROME) GENE ANALYSIS; FULL SEQUENCE ANALYSIS |
| 81322 | PTEN (PHOSPHATASE AND TENSIN HOMOLOG) (EG, COWDEN SYNDROME, PTEN HAMARTOMA TUMOR SYNDROME) GENE ANALYSIS; KNOWN FAMILIAL VARIANT |
| 81323 | PTEN (PHOSPHATASE AND TENSIN HOMOLOG) (EG, COWDEN SYNDROME, PTEN HAMARTOMA TUMOR SYNDROME) GENE ANALYSIS; DUPLICATION/DELETION VARIANT |
| 81400 | MOLECULAR PATHOLOGY PROCEDURE, LEVEL 1 (EG, IDENTIFICATION OF SINGLE GERMLINE VARIANT [EG, SNP] BY TECHNIQUES SUCH AS RESTRICTION ENZYME DIGESTION OR MELT CURVE ANALYSIS) |
| 81401 | MOLECULAR PATHOLOGY PROCEDURE, LEVEL 2 (EG, 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 (EG, >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 OF 1 EXON, LOSS OF HETEROZYGOSITY [LOH], UNIPARENTAL DISOMY [UPD]) |
| 81403 | |

MOLECULAR PATHOLOGY PROCEDURE, LEVEL 4 (EG, 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 (EG, 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)

81405 MOLECULAR PATHOLOGY PROCEDURE, LEVEL 6 (EG, 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 (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)

81479 UNLISTED MOLECULAR PATHOLOGY PROCEDURE

81599 UNLISTED MULTIANALYTE ASSAY WITH ALGORITHMIC ANALYSIS

**Group 3 Paragraph: NON-COVERED MOLECULAR PATHOLOGY PROCEDURES**

Genetic testing procedures submitted under the following CPT codes are unlikely to impact therapeutic decision-making in the clinical management of the patient and will be denied automatically as not medically necessary:

**Group 3 Codes:**

0004M SCOLIOSIS, DNA ANALYSIS OF 53 SINGLE NUCLEOTIDE POLYMORPHISMS (SNPS), USING SALIVA, PROGNOSTIC ALGORITHM REPORTED AS A RISK SCORE

0006M ONCOLOGY (HEPATIC), MRNA EXPRESSION LEVELS OF 161 GENES, UTILIZING FRESH HEPATOCELLULAR CARCINOMA TUMOR TISSUE, WITH ALPHA-FETOPROTEIN LEVEL, ALGORITHM REPORTED AS A RISK CLASSIFIER

0007M ONCOLOGY (GASTROINTESTINAL NEUROENDOCRINE TUMORS), REAL-TIME PCR EXPRESSION ANALYSIS OF 51 GENES, UTILIZING WHOLE PERIPHERAL BLOOD, ALGORITHM REPORTED AS A NOMOGRAM OF TUMOR DISEASE INDEX

0009M FETAL ANEUPLOIDY (TRISOMY 21, AND 18) DNA SEQUENCE ANALYSIS OF SELECTED REGIONS USING MATERNAL PLASMA, ALGORITHM REPORTED AS A RISK SCORE FOR EACH TRISOMY

81161 DMD (DYSTROPHIN) (EG, DUCHENNE/BECKER MUSCULAR DYSTROPHY) DELETION ANALYSIS, AND DUPLICATION ANALYSIS, IF PERFORMED

81200 ASPA (ASPARTOACYLASE) (EG, CANAVAN DISEASE) GENE ANALYSIS, COMMON VARIANTS (EG, E285A, Y231X)

81201 APC (ADENOMATOUS POLYPOSIS COLI) (EG, FAMILIAL ADENOMATOSIS POLYPOSIS [FAP], ATTENUATED FAP) GENE ANALYSIS; FULL GENE SEQUENCE

81202 APC (ADENOMATOUS POLYPOSIS COLI) (EG, FAMILIAL ADENOMATOSIS POLYPOSIS [FAP], ATTENUATED FAP) GENE ANALYSIS; KNOWN FAMILIAL VARIANTS

81203 APC (ADENOMATOUS POLYPOSIS COLI) (EG, FAMILIAL ADENOMATOSIS POLYPOSIS [FAP], ATTENUATED FAP) GENE ANALYSIS; DUPLICATION/DELETION VARIANTS

81205 BCKDHB (BRANCHED-CHAIN KETO ACID DEHYDROGENASE E1, BETA POLYPEPTIDE) (EG, MAPLE SYRUP URINE DISEASE) GENE ANALYSIS, COMMON VARIANTS (EG, R183P, G278S, E422X)

81227 CYP2C9 (CYTOCHROME P450, FAMILY 2, SUBFAMILY C, POLYPEPTIDE 9) (EG, DRUG METABOLISM), GENE ANALYSIS, COMMON VARIANTS (EG, *2, *3, *5, *6)

81228 CYTOGENOMIC CONSTITUTIONAL (GENOME-WIDE) MICROARRAY ANALYSIS; INTERROGATION OF GENOMIC REGIONS FOR COPY NUMBER VARIANTS (EG, 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) (EG, HEREDITARY HYPERCOAGULABILITY) GENE ANALYSIS, 20210G>A VARIANT

81241 F5 (COAGULATION FACTOR V) (EG, HEREDITARY HYPERCOAGULABILITY) GENE ANALYSIS, LEIDEN VARIANT

81242 FANCC (FANCONI ANEMIA, COMPLEMENTATION GROUP C) (EG, FANCONI ANEMIA, TYPE C) GENE ANALYSIS, COMMON VARIANT (EG, IVS4+4A>T)

81243 FMR1 (FRAGILE X MENTAL RETARDATION 1) (EG, FRAGILE X MENTAL RETARDATION) GENE ANALYSIS; EVALUATION TO DETECT ABNORMAL (EG, EXPANDED) ALLELES

81244

FMR1 (FRAGILE X MENTAL RETARDATION 1) (EG, FRAGILE X MENTAL RETARDATION) GENE ANALYSIS; CHARACTERIZATION OF ALLELES (EG, EXPANDED SIZE AND METHYLATION STATUS)

81250 G6PC (GLUCOSE-6-PHOSPHATASE, CATALYTIC SUBUNIT) (EG, GLYCOGEN STORAGE DISEASE, TYPE 1A, VON GIERKE DISEASE) GENE ANALYSIS, COMMON VARIANTS (EG, R83C, Q347X)

81251 GBA (GLUCOSIDASE, BETA, ACID) (EG, GAUCHER DISEASE) GENE ANALYSIS, COMMON VARIANTS (EG, N370S, 84GG, L444P, IVS2+1G>A)

81252 GJB2 (GAP JUNCTION PROTEIN, BETA 2, 26KDA, CONNEXIN 26) (EG, NONSYNDROMIC HEARING LOSS) GENE ANALYSIS; FULL GENE SEQUENCE

81253 GJB2 (GAP JUNCTION PROTEIN, BETA 2, 26KDA, CONNEXIN 26) (EG, NONSYNDROMIC HEARING LOSS) GENE ANALYSIS; KNOWN FAMILIAL VARIANTS

81254 GJB6 (GAP JUNCTION PROTEIN, BETA 6, 30KDA, CONNEXIN 30) (EG, NONSYNDROMIC HEARING LOSS) GENE ANALYSIS, COMMON VARIANTS (EG, 309KB [DEL(GJB6-D13S1830)] AND 232KB [DEL(GJB6-D13S1854)])

81255 HEXA (HEXOSAMINIDASE A [ALPHA POLYPEPTIDE]) (EG, TAY-SACHS DISEASE) GENE ANALYSIS, COMMON VARIANTS (EG, 1278INSTATC, 1421+1G>C, G269S)

81257 HBA1/HBA2 (ALPHA GLOBIN 1 AND ALPHA GLOBIN 2) (EG, ALPHA THALASSEMIA, HB BART HYDROPS FETALIS SYNDROME, HBH DISEASE), GENE ANALYSIS, FOR COMMON DELETIONS OR VARIANT (EG, 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) (EG, FAMILIAL DYSAUTONOMIA) GENE ANALYSIS, COMMON VARIANTS (EG, 2507+6T>C, R696P)

81290 MCOLN1 (MUCOLIPIN 1) (EG, MUCOLIPIDOSIS, TYPE IV) GENE ANALYSIS, COMMON VARIANTS (EG, IVS3 -2A>G, DEL6.4KB)

81291 MTHFR (5,10-METHYLENETETRAHYDROFOLATE REDUCTASE) (EG, HEREDITARY HYPERCOAGULABILITY) GENE ANALYSIS, COMMON VARIANTS (EG, 677T, 1298C)

81302 MECP2 (METHYL CPG BINDING PROTEIN 2) (EG, RETT SYNDROME) GENE ANALYSIS; FULL SEQUENCE ANALYSIS

81303 MECP2 (METHYL CPG BINDING PROTEIN 2) (EG, RETT SYNDROME) GENE ANALYSIS; KNOWN FAMILIAL VARIANT

81304 MECP2 (METHYL CPG BINDING PROTEIN 2) (EG, RETT SYNDROME) GENE ANALYSIS; DUPLICATION/DELETION VARIANTS

81324 PMP22 (PERIPHERAL MYELIN PROTEIN 22) (EG, CHARCOT-MARIE-TOOTH, HEREDITARY NEUROPATHY WITH LIABILITY TO PRESSURE PALSIES) GENE ANALYSIS; DUPLICATION/DELETION ANALYSIS

81325 PMP22 (PERIPHERAL MYELIN PROTEIN 22) (EG, CHARCOT-MARIE-TOOTH, HEREDITARY NEUROPATHY WITH LIABILITY TO PRESSURE PALSIES) GENE ANALYSIS; FULL SEQUENCE ANALYSIS

81326 PMP22 (PERIPHERAL MYELIN PROTEIN 22) (EG, CHARCOT-MARIE-TOOTH, HEREDITARY NEUROPATHY WITH LIABILITY TO PRESSURE PALSIES) GENE ANALYSIS; KNOWN FAMILIAL VARIANT

81330 SMPD1(SPHINGOMYELIN PHOSPHODIESTERASE 1, ACID LYSOSOMAL) (EG, NIEMANN-PICK DISEASE, TYPE A) GENE ANALYSIS, COMMON VARIANTS (EG, R496L, L302P, FSP330)

81331 SNRPN/UBE3A (SMALL NUCLEAR RIBONUCLEOPROTEIN POLYPEPTIDE N AND UBIQUITIN PROTEIN LIGASE E3A) (EG, PRADER-WILLI SYNDROME AND/OR ANGELMAN SYNDROME), METHYLATION ANALYSIS

81350 UGT1A1 (UDP GLUCURONOSYLTRANSFERASE 1 FAMILY, POLYPEPTIDE A1) (EG, IRINOTECAN METABOLISM), 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)

81407 MOLECULAR PATHOLOGY PROCEDURE, LEVEL 8 (EG, 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 (EG, ANALYSIS OF >50 EXONS IN A SINGLE GENE BY DNA SEQUENCE ANALYSIS)

81410 AORTIC DYSFUNCTION OR DILATION (EG, MARFAN SYNDROME, LOEYS DIETZ SYNDROME, EHLER DANLOS SYNDROME TYPE IV, ARTERIAL TORTUOSITY SYNDROME); GENOMIC SEQUENCE ANALYSIS PANEL, MUST INCLUDE SEQUENCING OF AT LEAST 9 GENES, INCLUDING FBN1, TGFBR1, TGFBR2, COL3A1, MYH11, ACTA2, SLC2A10, SMAD3, AND MYLK

81411 AORTIC DYSFUNCTION OR DILATION (EG, MARFAN SYNDROME, LOEYS DIETZ SYNDROME, EHLER DANLOS SYNDROME TYPE IV, ARTERIAL TORTUOSITY SYNDROME); DUPLICATION/DELETION ANALYSIS PANEL, MUST INCLUDE ANALYSES FOR TGFBR1, TGFBR2, MYH11, AND COL3A1

81412 ASHKENAZI JEWISH ASSOCIATED DISORDERS (EG, BLOOM SYNDROME, CANAVAN DISEASE, CYSTIC FIBROSIS, FAMILIAL DYSAUTONOMIA, FANCONI ANEMIA GROUP C, GAUCHER DISEASE, TAY-SACHS DISEASE), GENOMIC SEQUENCE ANALYSIS PANEL, MUST INCLUDE SEQUENCING OF AT LEAST 9 GENES, INCLUDING ASPA, BLM, CFTR, FANCC, GBA, HEXA, IKBKAP, MCOLN1, AND SMPD1

81413

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| | CARDIAC ION CHANNELOPATHIES (EG, BRUGADA SYNDROME, LONG QT SYNDROME, SHORT QT SYNDROME, CATECHOLAMINERGIC POLYMORPHIC VENTRICULAR TACHYCARDIA); GENOMIC SEQUENCE ANALYSIS PANEL, MUST INCLUDE SEQUENCING OF AT LEAST 10 GENES, INCLUDING ANK2, CASQ2, CAV3, KCNE1, KCNE2, KCNH2, KCNJ2, KCNQ1, RYR2, AND SCN5A |
| 81414 | CARDIAC ION CHANNELOPATHIES (EG, BRUGADA SYNDROME, LONG QT SYNDROME, SHORT QT SYNDROME, CATECHOLAMINERGIC POLYMORPHIC VENTRICULAR TACHYCARDIA); DUPLICATION/DELETION GENE ANALYSIS PANEL, MUST INCLUDE ANALYSIS OF AT LEAST 2 GENES, INCLUDING KCNH2 AND KCNQ1 |
| 81415 | EXOME (EG, UNEXPLAINED CONSTITUTIONAL OR HERITABLE DISORDER OR SYNDROME); SEQUENCE ANALYSIS |
| 81416 | EXOME (EG, UNEXPLAINED CONSTITUTIONAL OR HERITABLE DISORDER OR SYNDROME); SEQUENCE ANALYSIS, EACH COMPARATOR EXOME (EG, PARENTS, SIBLINGS) (LIST SEPARATELY IN ADDITION TO CODE FOR PRIMARY PROCEDURE) |
| 81417 | EXOME (EG, UNEXPLAINED CONSTITUTIONAL OR HERITABLE DISORDER OR SYNDROME); RE-EVALUATION OF PREVIOUSLY OBTAINED EXOME SEQUENCE (EG, UPDATED KNOWLEDGE OR UNRELATED CONDITION/SYNDROME) |
| 81420 | FETAL CHROMOSOMAL ANEUPLOIDY (EG, TRISOMY 21, MONOSOMY X) GENOMIC SEQUENCE ANALYSIS PANEL, CIRCULATING CELL-FREE FETAL DNA IN MATERNAL BLOOD, MUST INCLUDE ANALYSIS OF CHROMOSOMES 13, 18, AND 21 |
| 81422 | FETAL CHROMOSOMAL MICRODELETION(S) GENOMIC SEQUENCE ANALYSIS (EG, DIGEORGE SYNDROME, CRI-DU-CHAT SYNDROME), CIRCULATING CELL-FREE FETAL DNA IN MATERNAL BLOOD |
| 81425 | GENOME (EG, UNEXPLAINED CONSTITUTIONAL OR HERITABLE DISORDER OR SYNDROME); SEQUENCE ANALYSIS |
| 81426 | GENOME (EG, UNEXPLAINED CONSTITUTIONAL OR HERITABLE DISORDER OR SYNDROME); SEQUENCE ANALYSIS, EACH COMPARATOR GENOME (EG, PARENTS, SIBLINGS) (LIST SEPARATELY IN ADDITION TO CODE FOR PRIMARY PROCEDURE) |
| 81427 | GENOME (EG, UNEXPLAINED CONSTITUTIONAL OR HERITABLE DISORDER OR SYNDROME); RE-EVALUATION OF PREVIOUSLY OBTAINED GENOME SEQUENCE (EG, UPDATED KNOWLEDGE OR UNRELATED CONDITION/SYNDROME) |
| 81430 | HEARING LOSS (EG, NONSYNDROMIC HEARING LOSS, USHER SYNDROME, PENDRED SYNDROME); GENOMIC SEQUENCE ANALYSIS PANEL, MUST INCLUDE SEQUENCING OF AT LEAST 60 GENES, INCLUDING CDH23, CLRN1, GJB2, GPR98, MTRNR1, MYO7A, MYO15A, PCDH15, OTOF, SLC26A4, TMC1, TMPRSS3, USH1C, USH1G, USH2A, AND WFS1 |
| 81431 | HEARING LOSS (EG, NONSYNDROMIC HEARING LOSS, USHER SYNDROME, PENDRED SYNDROME); DUPLICATION/DELETION ANALYSIS PANEL, MUST INCLUDE COPY NUMBER ANALYSES FOR STRC AND DFNB1 DELETIONS IN GJB2 AND GJB6 GENES |
| 81432 | HEREDITARY BREAST CANCER-RELATED DISORDERS (EG, HEREDITARY BREAST CANCER, HEREDITARY OVARIAN CANCER, HEREDITARY ENDOMETRIAL CANCER); GENOMIC SEQUENCE ANALYSIS PANEL, MUST INCLUDE SEQUENCING OF AT LEAST 14 GENES, INCLUDING ATM, BRCA1, BRCA2, BRIP1, CDH1, MLH1, MSH2, MSH6, NBN, PALB2, PTEN, RAD51C, STK11, AND TP53 |
| 81433 | HEREDITARY BREAST CANCER-RELATED DISORDERS (EG, HEREDITARY BREAST CANCER, HEREDITARY OVARIAN CANCER, HEREDITARY ENDOMETRIAL CANCER); DUPLICATION/DELETION ANALYSIS PANEL, MUST INCLUDE ANALYSES FOR BRCA1, BRCA2, MLH1, MSH2, AND STK11 |
| 81434 | HEREDITARY RETINAL DISORDERS (EG, RETINITIS PIGMENTOSA, LEBER CONGENITAL AMAUROSIS, CONE-ROD DYSTROPHY), GENOMIC SEQUENCE ANALYSIS PANEL, MUST INCLUDE SEQUENCING OF AT LEAST 15 GENES, INCLUDING ABCA4, CNGA1, CRB1, EYS, PDE6A, PDE6B, PRPF31, PRPH2, RDH12, RHO, RP1, RP2, RPE65, RPGR, AND USH2A |
| 81435 | HEREDITARY COLON CANCER DISORDERS (EG, LYNCH SYNDROME, PTEN HAMARTOMA SYNDROME, COWDEN SYNDROME, FAMILIAL ADENOMATOSIS POLYPOSIS); GENOMIC SEQUENCE ANALYSIS PANEL, MUST INCLUDE SEQUENCING OF AT LEAST 10 GENES, INCLUDING APC, BMPR1A, CDH1, MLH1, MSH2, MSH6, MUTYH, PTEN, SMAD4, AND STK11 |
| 81436 | HEREDITARY COLON CANCER DISORDERS (EG, LYNCH SYNDROME, PTEN HAMARTOMA SYNDROME, COWDEN SYNDROME, FAMILIAL ADENOMATOSIS POLYPOSIS); DUPLICATION/DELETION ANALYSIS PANEL, MUST INCLUDE ANALYSIS OF AT LEAST 5 GENES, INCLUDING MLH1, MSH2, EPCAM, SMAD4, AND STK11 |
| 81437 | HEREDITARY NEUROENDOCRINE TUMOR DISORDERS (EG, MEDULLARY THYROID CARCINOMA, PARATHYROID CARCINOMA, MALIGNANT PHEOCHROMOCYTOMA OR PARAGANGLIOMA); GENOMIC SEQUENCE ANALYSIS PANEL, MUST INCLUDE SEQUENCING OF AT LEAST 6 GENES, INCLUDING MAX, SDHB, SDHC, SDHD, TMEM127, AND VHL |
| 81438 | HEREDITARY NEUROENDOCRINE TUMOR DISORDERS (EG, MEDULLARY THYROID CARCINOMA, PARATHYROID CARCINOMA, MALIGNANT PHEOCHROMOCYTOMA OR PARAGANGLIOMA); DUPLICATION/DELETION ANALYSIS PANEL, MUST INCLUDE ANALYSES FOR SDHB, SDHC, SDHD, AND VHL |
| 81439 | |

INHERITED CARDIOMYOPATHY (EG, HYPERTROPHIC CARDIOMYOPATHY, DILATED CARDIOMYOPATHY, ARRHYTHMOGENIC RIGHT VENTRICULAR CARDIOMYOPATHY) GENOMIC SEQUENCE ANALYSIS PANEL, MUST INCLUDE SEQUENCING OF AT LEAST 5 GENES, INCLUDING DSG2, MYBPC3, MYH7, PKP2, AND TTN

81440 NUCLEAR ENCODED MITOCHONDRIAL GENES (EG, NEUROLOGIC OR MYOPATHIC PHENOTYPES), GENOMIC SEQUENCE PANEL, MUST INCLUDE ANALYSIS OF AT LEAST 100 GENES, INCLUDING BCS1L, C10ORF2, COQ2, COX10, DGUOK, MPV17, OPA1, PDSS2, POLG, POLG2, RRM2B, SCO1, SCO2, SLC25A4, SUCLA2, SUCLG1, TAZ, TK2, AND TYMP

81442 NOONAN SPECTRUM DISORDERS (EG, NOONAN SYNDROME, CARDIO-FACIO-CUTANEOUS SYNDROME, COSTELLO SYNDROME, LEOPARD SYNDROME, NOONAN-LIKE SYNDROME), GENOMIC SEQUENCE ANALYSIS PANEL, MUST INCLUDE SEQUENCING OF AT LEAST 12 GENES, INCLUDING BRAF, CBL, HRAS, KRAS, MAP2K1, MAP2K2, NRAS, PTPN11, RAF1, RIT1, SHOC2, AND SOS1

81455 TARGETED GENOMIC SEQUENCE ANALYSIS PANEL, SOLID ORGAN OR HEMATOLYMPHOID NEOPLASM, DNA ANALYSIS, AND RNA ANALYSIS WHEN PERFORMED, 51 OR GREATER GENES (EG, ALK, BRAF, CDKN2A, CEBPA, DNMT3A, EGFR, ERBB2, EZH2, FLT3, IDH1, IDH2, JAK2, KIT, KRAS, MLL, NPM1, NRAS, MET, NOTCH1, PDGFRA, PDGFRB, PGR, PIK3CA, PTEN, RET), INTERROGATION FOR SEQUENCE VARIANTS AND COPY NUMBER VARIANTS OR REARRANGEMENTS, IF PERFORMED

81460 WHOLE MITOCHONDRIAL GENOME (EG, LEIGH SYNDROME, MITOCHONDRIAL ENCEPHALOMYOPATHY, LACTIC ACIDOSIS, AND STROKE-LIKE EPISODES [MELAS], MYOCLONIC EPILEPSY WITH RAGGED-RED FIBERS [MERFF], NEUROPATHY, ATAXIA, AND RETINITIS PIGMENTOSA [NARP], LEBER HEREDITARY OPTIC NEUROPATHY [LHON]), GENOMIC SEQUENCE, MUST INCLUDE SEQUENCE ANALYSIS OF ENTIRE MITOCHONDRIAL GENOME WITH HETEROPLASMY DETECTION

81465 WHOLE MITOCHONDRIAL GENOME LARGE DELETION ANALYSIS PANEL (EG, KEARNS-SAYRE SYNDROME, CHRONIC PROGRESSIVE EXTERNAL OPHTHALMOPLEGIA), INCLUDING HETEROPLASMY DETECTION, IF PERFORMED

81470 X-LINKED INTELLECTUAL DISABILITY (XLID) (EG, SYNDROMIC AND NON-SYNDROMIC XLID); GENOMIC SEQUENCE ANALYSIS PANEL, MUST INCLUDE SEQUENCING OF AT LEAST 60 GENES, INCLUDING ARX, ATRX, CDKL5, FGD1, FMR1, HUWE1, IL1RAPL, KDM5C, L1CAM, MECP2, MED12, MID1, OCRL, RPS6KA3, AND SLC16A2

81471 X-LINKED INTELLECTUAL DISABILITY (XLID) (EG, SYNDROMIC AND NON-SYNDROMIC XLID); DUPLICATION/DELETION GENE ANALYSIS, MUST INCLUDE ANALYSIS OF AT LEAST 60 GENES, INCLUDING ARX, ATRX, CDKL5, FGD1, FMR1, HUWE1, IL1RAPL, KDM5C, L1CAM, MECP2, MED12, MID1, OCRL, RPS6KA3, AND SLC16A2

81493 CORONARY ARTERY DISEASE, MRNA, GENE EXPRESSION PROFILING BY REAL-TIME RT-PCR OF 23 GENES, UTILIZING WHOLE PERIPHERAL BLOOD, ALGORITHM REPORTED AS A RISK SCORE

81500 ONCOLOGY (OVARIAN), BIOCHEMICAL ASSAYS OF TWO PROTEINS (CA-125 AND HE4), UTILIZING SERUM, WITH MENOPAUSAL STATUS, ALGORITHM REPORTED AS A RISK SCORE

81503 ONCOLOGY (OVARIAN), BIOCHEMICAL ASSAYS OF FIVE PROTEINS (CA-125, APOLIPOPROTEIN A1, BETA-2 MICROGLOBULIN, TRANSFERRIN, AND PRE-ALBUMIN), UTILIZING SERUM, ALGORITHM REPORTED AS A RISK SCORE

81504 ONCOLOGY (TISSUE OF ORIGIN), MICROARRAY GENE EXPRESSION PROFILING OF > 2000 GENES, UTILIZING FORMALIN-FIXED PARAFFIN-EMBEDDED TISSUE, ALGORITHM REPORTED AS TISSUE SIMILARITY SCORES

81507 FETAL ANEUPLOIDY (TRISOMY 21, 18, AND 13) DNA SEQUENCE ANALYSIS OF SELECTED REGIONS USING MATERNAL PLASMA, ALGORITHM REPORTED AS A RISK SCORE FOR EACH TRISOMY

81525 ONCOLOGY (COLON), MRNA, GENE EXPRESSION PROFILING BY REAL-TIME RT-PCR OF 12 GENES (7 CONTENT AND 5 HOUSEKEEPING), UTILIZING FORMALIN-FIXED PARAFFIN-EMBEDDED TISSUE, ALGORITHM REPORTED AS A RECURRENCE SCORE

81535 ONCOLOGY (GYNECOLOGIC), LIVE TUMOR CELL CULTURE AND CHEMOTHERAPEUTIC RESPONSE BY DAPI STAIN AND MORPHOLOGY, PREDICTIVE ALGORITHM REPORTED AS A DRUG RESPONSE SCORE; FIRST SINGLE DRUG OR DRUG COMBINATION

81536 ONCOLOGY (GYNECOLOGIC), LIVE TUMOR CELL CULTURE AND CHEMOTHERAPEUTIC RESPONSE BY DAPI STAIN AND MORPHOLOGY, PREDICTIVE ALGORITHM REPORTED AS A DRUG RESPONSE SCORE; EACH ADDITIONAL SINGLE DRUG OR DRUG COMBINATION (LIST SEPARATELY IN ADDITION TO CODE FOR PRIMARY PROCEDURE)

81538 ONCOLOGY (LUNG), MASS SPECTROMETRIC 8-PROTEIN SIGNATURE, INCLUDING AMYLOID A, UTILIZING SERUM, PROGNOSTIC AND PREDICTIVE ALGORITHM REPORTED AS GOOD VERSUS POOR OVERALL SURVIVAL

81540 ONCOLOGY (TUMOR OF UNKNOWN ORIGIN), MRNA, GENE EXPRESSION PROFILING BY REAL-TIME RT-PCR OF 92 GENES (87 CONTENT AND 5 HOUSEKEEPING) TO CLASSIFY TUMOR INTO MAIN CANCER TYPE AND SUBTYPE, UTILIZING FORMALIN-FIXED PARAFFIN-EMBEDDED TISSUE, ALGORITHM REPORTED AS A PROBABILITY OF A PREDICTED MAIN CANCER TYPE AND SUBTYPE

81545 ONCOLOGY (THYROID), GENE EXPRESSION ANALYSIS OF 142 GENES, UTILIZING FINE NEEDLE ASPIRATE, ALGORITHM REPORTED AS A CATEGORICAL RESULT (EG, BENIGN OR SUSPICIOUS)

ICD-10 Codes that Support Medical Necessity
**Group 1 Paragraph:** CPT codes 81162, 81211, 81212, 81213, 81214, 81215, 81216, 81217 are considered medically necessary for the following ICD-10-CM codes:

**Group 1 Codes:**

| ICD-10 Codes | Description |
|---|---|
| Z85.3 | Personal history of malignant neoplasm of breast |
| Z86.000 | Personal history of in-situ neoplasm of breast |

**Group 2 Paragraph:** CPT code 81170 is considered medically necessary for the following ICD-10-CM codes

**Group 2 Codes:**

| ICD-10 Codes | Description |
|---|---|
| C92.10 - C92.12 | Chronic myeloid leukemia, BCR/ABL-positive, not having achieved remission - Chronic myeloid leukemia, BCR/ABL-positive, in relapse |
| C92.20 - C92.22 | Atypical chronic myeloid leukemia, BCR/ABL-negative, not having achieved remission - Atypical chronic myeloid leukemia, BCR/ABL-negative, in relapse |

**Group 3 Paragraph:** CPT codes 81206, 81207, and 81208 (BCR/ABL) are considered medically necessary for the following ICD-10-CM codes:

**Group 3 Codes:**

| ICD-10 Codes | Description |
|---|---|
| C91.00 - C91.02 | Acute lymphoblastic leukemia not having achieved remission - Acute lymphoblastic leukemia, in relapse |
| C92.10 - C92.12 | Chronic myeloid leukemia, BCR/ABL-positive, not having achieved remission - Chronic myeloid leukemia, BCR/ABL-positive, in relapse |
| C92.20 - C92.22 | Atypical chronic myeloid leukemia, BCR/ABL-negative, not having achieved remission - Atypical chronic myeloid leukemia, BCR/ABL-negative, in relapse |
| C92.90 - C92.92 | Myeloid leukemia, unspecified, not having achieved remission - Myeloid leukemia, unspecified in relapse |

**Group 4 Paragraph:** CPT code 81210 (BRAF) is considered medically necessary for the following ICD-10-CM codes:

**Group 4 Codes:**

| ICD-10 Codes | Description |
|---|---|
| C17.0 - C17.9 | Malignant neoplasm of duodenum - Malignant neoplasm of small intestine, unspecified |
| C18.0 - C19 | Malignant neoplasm of cecum - Malignant neoplasm of rectosigmoid junction |
| C20 | Malignant neoplasm of rectum |
| C21.1 | Malignant neoplasm of anal canal |
| C21.2 | Malignant neoplasm of cloacogenic zone |
| C21.8 | Malignant neoplasm of overlapping sites of rectum, anus and anal canal |
| C33 - C34.92 | Malignant neoplasm of trachea - Malignant neoplasm of unspecified part of left bronchus or lung |
| C43.0 - C43.9 | Malignant melanoma of lip - Malignant melanoma of skin, unspecified |
| C78.4 | Secondary malignant neoplasm of small intestine |
| C78.5 | Secondary malignant neoplasm of large intestine and rectum |
| C91.40 - C91.42 | Hairy cell leukemia not having achieved remission - Hairy cell leukemia, in relapse |
| D03.0 - D03.9 | Melanoma in situ of lip - Melanoma in situ, unspecified |
| Z85.038 | Personal history of other malignant neoplasm of large intestine |
| Z85.048 | Personal history of other malignant neoplasm of rectum, rectosigmoid junction, and anus |

| ICD-10 Codes | Description |
|---|---|
| Z85.820 | Personal history of malignant melanoma of skin |

**Group 5 Paragraph:** CPT Code 81218 (CEBPA) is considered medically necessary for the following ICD-10-CM codes:

**Group 5 Codes:**

| ICD-10 Codes | Description |
|---|---|
| C92.00 | Acute myeloblastic leukemia, not having achieved remission |
| C92.02 | Acute myeloblastic leukemia, in relapse |
| C92.30 | Myeloid sarcoma, not having achieved remission |
| C92.32 | Myeloid sarcoma, in relapse |
| C92.40 | Acute promyelocytic leukemia, not having achieved remission |
| C92.42 | Acute promyelocytic leukemia, in relapse |
| C92.50 | Acute myelomonocytic leukemia, not having achieved remission |
| C92.52 | Acute myelomonocytic leukemia, in relapse |
| C92.60 | Acute myeloid leukemia with 11q23-abnormality not having achieved remission |
| C92.62 | Acute myeloid leukemia with 11q23-abnormality in relapse |
| C92.A0 | Acute myeloid leukemia with multilineage dysplasia, not having achieved remission |
| C92.A2 | Acute myeloid leukemia with multilineage dysplasia, in relapse |
| C92.Z0 | Other myeloid leukemia not having achieved remission |
| C92.Z2 | Other myeloid leukemia, in relapse |
| C94.00 | Acute erythroid leukemia, not having achieved remission |
| C94.02 | Acute erythroid leukemia, in relapse |

**Group 6 Paragraph:** CPT Code 81219 (CALR) is considered medically necessary for the following ICD-10-CM codes:

**Group 6 Codes:**

| ICD-10 Codes | Description |
|---|---|
| C88.8 | Other malignant immunoproliferative diseases |
| C94.40 | Acute panmyelosis with myelofibrosis not having achieved remission |
| C94.41 | Acute panmyelosis with myelofibrosis, in remission |
| C94.42 | Acute panmyelosis with myelofibrosis, in relapse |
| C94.6 | Myelodysplastic disease, not classified |
| D45 | Polycythemia vera |
| D46.0 | Refractory anemia without ring sideroblasts, so stated |
| D46.1 | Refractory anemia with ring sideroblasts |
| D46.20 | Refractory anemia with excess of blasts, unspecified |
| D46.21 | Refractory anemia with excess of blasts 1 |
| D46.22 | Refractory anemia with excess of blasts 2 |
| D46.A | Refractory cytopenia with multilineage dysplasia |
| D46.B | Refractory cytopenia with multilineage dysplasia and ring sideroblasts |
| D46.C | Myelodysplastic syndrome with isolated del(5q) chromosomal abnormality |
| D46.4 | Refractory anemia, unspecified |
| D46.Z | Other myelodysplastic syndromes |
| D46.9 | Myelodysplastic syndrome, unspecified |
| D47.1 | Chronic myeloproliferative disease |
| D47.3 | Essential (hemorrhagic) thrombocythemia |
| D47.4 | Osteomyelofibrosis |
| D47.Z9 | Other specified neoplasms of uncertain behavior of lymphoid, hematopoietic and related tissue |
| D47.9 | Neoplasm of uncertain behavior of lymphoid, hematopoietic and related tissue, unspecified |
| D72.821 | Monocytosis (symptomatic) |
| D72.829 | Elevated white blood cell count, unspecified |
| D75.1 | Secondary polycythemia |
| D75.81 | Myelofibrosis |
| D75.89 | Other specified diseases of blood and blood-forming organs |

| ICD-10 Codes | Description |
|---|---|
| D75.9 | Disease of blood and blood-forming organs, unspecified |

**Group 7 Paragraph:** CPT Code 81313 (PCA3) is considered medically necessary for the following ICD-10-CM code:

**Group 7 Codes:**

| ICD-10 Codes | Description |
|---|---|
| R97.20 | Elevated prostate specific antigen [PSA] |

**Group 8 Paragraph:** CPT codes 81315 and 81316 PML/RARALPHA are considered medically necessary for the following ICD-10-CM codes:

**Group 8 Codes:**

| ICD-10 Codes | Description |
|---|---|
| C92.40 - C92.42 | Acute promyelocytic leukemia, not having achieved remission - Acute promyelocytic leukemia, in relapse |

**Group 9 Paragraph:** CPT code 81225 (CYP2C19) is considered medically necessary for the following ICD-10-CM codes:

**Group 9 Codes:**

| ICD-10 Codes | Description |
|---|---|
| I20.0 | Unstable angina |
| I20.1 | Angina pectoris with documented spasm |
| I20.8 | Other forms of angina pectoris |
| I20.9 | Angina pectoris, unspecified |
| I21.11 | ST elevation (STEMI) myocardial infarction involving right coronary artery |
| I21.19 | ST elevation (STEMI) myocardial infarction involving other coronary artery of inferior wall |
| I21.29 | ST elevation (STEMI) myocardial infarction involving other sites |
| I21.3 | ST elevation (STEMI) myocardial infarction of unspecified site |
| I21.4 | Non-ST elevation (NSTEMI) myocardial infarction |
| I24.0 | Acute coronary thrombosis not resulting in myocardial infarction |
| I24.1 | Dressler's syndrome |
| I24.8 | Other forms of acute ischemic heart disease |
| I24.9 | Acute ischemic heart disease, unspecified |
| I25.110 | Atherosclerotic heart disease of native coronary artery with unstable angina pectoris |
| I25.118 | Atherosclerotic heart disease of native coronary artery with other forms of angina pectoris |
| I25.119 | Atherosclerotic heart disease of native coronary artery with unspecified angina pectoris |
| I25.700 | Atherosclerosis of coronary artery bypass graft(s), unspecified, with unstable angina pectoris |
| I25.701 | Atherosclerosis of coronary artery bypass graft(s), unspecified, with angina pectoris with documented spasm |
| I25.708 | Atherosclerosis of coronary artery bypass graft(s), unspecified, with other forms of angina pectoris |
| I25.710 | Atherosclerosis of autologous vein coronary artery bypass graft(s) with unstable angina pectoris |
| I25.711 | Atherosclerosis of autologous vein coronary artery bypass graft(s) with angina pectoris with documented spasm |
| I25.718 | Atherosclerosis of autologous vein coronary artery bypass graft(s) with other forms of angina pectoris |
| I25.719 - I25.721 | Atherosclerosis of autologous vein coronary artery bypass graft(s) with unspecified angina pectoris - Atherosclerosis of autologous artery coronary artery bypass graft(s) with angina pectoris with documented spasm |
| I25.728 - I25.731 | Atherosclerosis of autologous artery coronary artery bypass graft(s) with other forms of angina pectoris - Atherosclerosis of nonautologous biological coronary artery bypass graft(s) with angina pectoris with documented spasm |
| I25.738 | Atherosclerosis of nonautologous biological coronary artery bypass graft(s) with other forms of angina pectoris |

| ICD-10 Codes | Description |
|---|---|
| I25.739 | Atherosclerosis of nonautologous biological coronary artery bypass graft(s) with unspecified angina pectoris |
| I25.750 | Atherosclerosis of native coronary artery of transplanted heart with unstable angina |
| I25.751 | Atherosclerosis of native coronary artery of transplanted heart with angina pectoris with documented spasm |
| I25.758 - I25.761 | Atherosclerosis of native coronary artery of transplanted heart with other forms of angina pectoris - Atherosclerosis of bypass graft of coronary artery of transplanted heart with angina pectoris with documented spasm |
| I25.769 | Atherosclerosis of bypass graft of coronary artery of transplanted heart with unspecified angina pectoris |
| I25.790 | Atherosclerosis of other coronary artery bypass graft(s) with unstable angina pectoris |
| I25.791 | Atherosclerosis of other coronary artery bypass graft(s) with angina pectoris with documented spasm |
| I25.798 | Atherosclerosis of other coronary artery bypass graft(s) with other forms of angina pectoris |
| I25.799 | Atherosclerosis of other coronary artery bypass graft(s) with unspecified angina pectoris |

**Group 10 Paragraph:** CPT code 81226 (CYP2d6) is considered medically necessary for the following ICD-10-CM codes:

**Group 10 Codes:**

| ICD-10 Codes | Description |
|---|---|
| E75.22 | Gaucher disease |
| G10 | Huntington's disease |

**Group 11 Paragraph:** CPT code 81235 (EGFR) is considered medically necessary for the following ICD-10-CM codes:

**Group 11 Codes:**

| ICD-10 Codes | Description |
|---|---|
| C33 - C34.92 | Malignant neoplasm of trachea - Malignant neoplasm of unspecified part of left bronchus or lung |

**Group 12 Paragraph:** CPT code 81245, 81246 (FLT3) are considered medically necessary for the following ICD-10-CM codes:

**Group 12 Codes:**

| ICD-10 Codes | Description |
|---|---|
| C92.00 | Acute myeloblastic leukemia, not having achieved remission |
| C92.02 | Acute myeloblastic leukemia, in relapse |
| C92.30 | Myeloid sarcoma, not having achieved remission |
| C92.32 | Myeloid sarcoma, in relapse |
| C92.40 | Acute promyelocytic leukemia, not having achieved remission |
| C92.42 | Acute promyelocytic leukemia, in relapse |
| C92.50 | Acute myelomonocytic leukemia, not having achieved remission |
| C92.52 | Acute myelomonocytic leukemia, in relapse |
| C92.60 | Acute myeloid leukemia with 11q23-abnormality not having achieved remission |
| C92.62 | Acute myeloid leukemia with 11q23-abnormality in relapse |
| C92.A0 | Acute myeloid leukemia with multilineage dysplasia, not having achieved remission |
| C92.A2 | Acute myeloid leukemia with multilineage dysplasia, in relapse |
| C92.Z0 | Other myeloid leukemia not having achieved remission |
| C92.Z2 | Other myeloid leukemia, in relapse |
| C94.00 | Acute erythroid leukemia, not having achieved remission |
| C94.02 | Acute erythroid leukemia, in relapse |

**Group 13 Paragraph:** CPT code 81256 (HFE) is considered medically necessary the following ICD-10-CM codes:

**Group 13 Codes:**

| ICD-10 Codes | Description |
|---|---|
| E83.10 | Disorder of iron metabolism, unspecified |
| E83.110 | Hereditary hemochromatosis |
| E83.118 | Other hemochromatosis |
| E83.119 | Hemochromatosis, unspecified |
| E83.19 | Other disorders of iron metabolism |

**Group 14 Paragraph:** CPT codes 81261-81264 (IGH) are considered medically necessary for the following ICD-10-CM codes:

**Group 14 Codes:**

| ICD-10 Codes | Description |
|---|---|
| C82.00 - C83.99 | Follicular lymphoma grade I, unspecified site - Non-follicular (diffuse) lymphoma, unspecified, extranodal and solid organ sites |
| C85.20 - C85.29 | Mediastinal (thymic) large B-cell lymphoma, unspecified site - Mediastinal (thymic) large B-cell lymphoma, extranodal and solid organ sites |
| C92.00 | Acute myeloblastic leukemia, not having achieved remission |
| C92.02 | Acute myeloblastic leukemia, in relapse |
| C92.30 | Myeloid sarcoma, not having achieved remission |
| C92.32 | Myeloid sarcoma, in relapse |
| C92.40 | Acute promyelocytic leukemia, not having achieved remission |
| C92.42 | Acute promyelocytic leukemia, in relapse |
| C92.50 | Acute myelomonocytic leukemia, not having achieved remission |
| C92.52 | Acute myelomonocytic leukemia, in relapse |
| C92.60 | Acute myeloid leukemia with 11q23-abnormality not having achieved remission |
| C92.62 | Acute myeloid leukemia with 11q23-abnormality in relapse |
| C92.A0 | Acute myeloid leukemia with multilineage dysplasia, not having achieved remission |
| C92.A2 | Acute myeloid leukemia with multilineage dysplasia, in relapse |
| C92.Z0 | Other myeloid leukemia not having achieved remission |
| C92.Z2 | Other myeloid leukemia, in relapse |
| C94.00 | Acute erythroid leukemia, not having achieved remission |
| C94.02 | Acute erythroid leukemia, in relapse |
| C95.00 - C95.92 | Acute leukemia of unspecified cell type not having achieved remission - Leukemia, unspecified, in relapse |
| D72.828 | Other elevated white blood cell count |
| D72.89 | Other specified disorders of white blood cells |

**Group 15 Paragraph:** CPT codes 81270 (JAK2), 81402 (MPL), 81403 (MPL) are considered medically necessary for the following ICD-10-CM codes when criteria in Indications and Limitations of Coverage are met:

**Group 15 Codes:**

| ICD-10 Codes | Description |
|---|---|
| C88.8 | Other malignant immunoproliferative diseases |
| C94.40 | Acute panmyelosis with myelofibrosis not having achieved remission |
| C94.41 | Acute panmyelosis with myelofibrosis, in remission |
| C94.42 | Acute panmyelosis with myelofibrosis, in relapse |
| C94.6 | Myelodysplastic disease, not classified |
| D45 | Polycythemia vera |

| ICD-10 Codes | Description |
|---|---|
| D46.0 | Refractory anemia without ring sideroblasts, so stated |
| D46.1 | Refractory anemia with ring sideroblasts |
| D46.20 | Refractory anemia with excess of blasts, unspecified |
| D46.21 | Refractory anemia with excess of blasts 1 |
| D46.22 | Refractory anemia with excess of blasts 2 |
| D46.A | Refractory cytopenia with multilineage dysplasia |
| D46.B | Refractory cytopenia with multilineage dysplasia and ring sideroblasts |
| D46.C | Myelodysplastic syndrome with isolated del(5q) chromosomal abnormality |
| D46.4 | Refractory anemia, unspecified |
| D46.Z | Other myelodysplastic syndromes |
| D46.9 | Myelodysplastic syndrome, unspecified |
| D47.1 | Chronic myeloproliferative disease |
| D47.3 | Essential (hemorrhagic) thrombocythemia |
| D47.4 | Osteomyelofibrosis |
| D47.Z9 | Other specified neoplasms of uncertain behavior of lymphoid, hematopoietic and related tissue |
| D47.9 | Neoplasm of uncertain behavior of lymphoid, hematopoietic and related tissue, unspecified |
| D72.821 | Monocytosis (symptomatic) |
| D72.829 | Elevated white blood cell count, unspecified |
| D75.1 | Secondary polycythemia |
| D75.81 | Myelofibrosis |
| D75.89 | Other specified diseases of blood and blood-forming organs |
| D75.9 | Disease of blood and blood-forming organs, unspecified |

**Group 16 Paragraph:**
CPT code 81272 (KIT) is considered medically necessary for the following ICD-10-CM codes:

CPT code 81273 (KIT) is considered medically necessary only for the diagnosis of mastocytosis*.

**Group 16 Codes:**

| ICD-10 Codes | Description |
|---|---|
| C43.0 - C43.9 | Malignant melanoma of lip - Malignant melanoma of skin, unspecified |
| C49.A0 - C49.A9 | Gastrointestinal stromal tumor, unspecified site - Gastrointestinal stromal tumor of other sites |
| C92.00 | Acute myeloblastic leukemia, not having achieved remission |
| C92.02 | Acute myeloblastic leukemia, in relapse |
| C92.30 | Myeloid sarcoma, not having achieved remission |
| C92.32 | Myeloid sarcoma, in relapse |
| C92.40 | Acute promyelocytic leukemia, not having achieved remission |
| C92.42 | Acute promyelocytic leukemia, in relapse |
| C92.50 | Acute myelomonocytic leukemia, not having achieved remission |
| C92.52 | Acute myelomonocytic leukemia, in relapse |
| C92.60 | Acute myeloid leukemia with 11q23-abnormality not having achieved remission |
| C92.62 | Acute myeloid leukemia with 11q23-abnormality in relapse |
| C92.A0 | Acute myeloid leukemia with multilineage dysplasia, not having achieved remission |
| C92.A2 | Acute myeloid leukemia with multilineage dysplasia, in relapse |
| C92.Z0 | Other myeloid leukemia not having achieved remission |
| C92.Z2 | Other myeloid leukemia, in relapse |
| C94.00 | Acute erythroid leukemia, not having achieved remission |
| C94.02 | Acute erythroid leukemia, in relapse |
| C96.2* | Malignant mast cell tumor |
| D03.0 - D03.9 | Melanoma in situ of lip - Melanoma in situ, unspecified |
| D47.0* | Histiocytic and mast cell tumors of uncertain behavior |
| D48.1 | Neoplasm of uncertain behavior of connective and other soft tissue |
| Z85.820 | Personal history of malignant melanoma of skin |

**Group 16 Medical Necessity ICD-10 Codes Asterisk Explanation:** CPT code 81273 (KIT) is considered medically necessary only for the diagnosis of mastocytosis*.

**Group 17 Paragraph:** CPT code 81275 and 81276 (KRAS) are considered medically necessary for the following ICD-10-CM codes:

**Group 17 Codes:**

| ICD-10 Codes | Description |
|---|---|
| C17.0 - C17.9 | Malignant neoplasm of duodenum - Malignant neoplasm of small intestine, unspecified |
| C18.0 - C19 | Malignant neoplasm of cecum - Malignant neoplasm of rectosigmoid junction |
| C20 | Malignant neoplasm of rectum |
| C21.1 | Malignant neoplasm of anal canal |
| C21.2 | Malignant neoplasm of cloacogenic zone |
| C21.8 | Malignant neoplasm of overlapping sites of rectum, anus and anal canal |
| C33 - C34.92 | Malignant neoplasm of trachea - Malignant neoplasm of unspecified part of left bronchus or lung |
| Z85.038 | Personal history of other malignant neoplasm of large intestine |
| Z85.048 | Personal history of other malignant neoplasm of rectum, rectosigmoid junction, and anus |

**Group 18 Paragraph:** CPT code 81287 (MGMT) is considered medically necessary for the following ICD-10-CM codes:

**Group 18 Codes:**

| ICD-10 Codes | Description |
|---|---|
| C71.0 - C71.9 | Malignant neoplasm of cerebrum, except lobes and ventricles - Malignant neoplasm of brain, unspecified |

**Group 19 Paragraph:** CPT code 81301 Microsatellite instability analysis (e.g., hereditary non-polyposis colorectal cancer, Lynch syndrome) is considered medically necessary for the following ICD-10-CM codes:

**Group 19 Codes:**

| ICD-10 Codes | Description |
|---|---|
| C17.0 - C17.9 | Malignant neoplasm of duodenum - Malignant neoplasm of small intestine, unspecified |
| C18.0 - C19 | Malignant neoplasm of cecum - Malignant neoplasm of rectosigmoid junction |
| C20 | Malignant neoplasm of rectum |
| C21.1 | Malignant neoplasm of anal canal |
| C21.2 | Malignant neoplasm of cloacogenic zone |
| C21.8 | Malignant neoplasm of overlapping sites of rectum, anus and anal canal |
| C33 - C34.92 | Malignant neoplasm of trachea - Malignant neoplasm of unspecified part of left bronchus or lung |
| Z85.038 | Personal history of other malignant neoplasm of large intestine |
| Z85.048 | Personal history of other malignant neoplasm of rectum, rectosigmoid junction, and anus |

**Group 20 Paragraph:** CPT Code 81311 (NRAS) is considered medically necessary for the following ICD-10-CM codes

**Group 20 Codes:**

| ICD-10 Codes | Description |
|---|---|
| C17.0 - C17.9 | Malignant neoplasm of duodenum - Malignant neoplasm of small intestine, unspecified |
| C18.0 - C19 | Malignant neoplasm of cecum - Malignant neoplasm of rectosigmoid junction |
| C20 | Malignant neoplasm of rectum |
| C21.1 | Malignant neoplasm of anal canal |
| C21.2 | Malignant neoplasm of cloacogenic zone |
| C21.8 | Malignant neoplasm of overlapping sites of rectum, anus and anal canal |
| Z85.038 | Personal history of other malignant neoplasm of large intestine |
| Z85.048 | Personal history of other malignant neoplasm of rectum, rectosigmoid junction, and anus |

**Group 21 Paragraph:** CPT Code 81314 (PDGFRA only) is considered medically necessary for the following ICD-10-CM codes:

**Group 21 Codes:**

| ICD-10 Codes | Description |
|---|---|
| C92.10 - C92.12 | Chronic myeloid leukemia, BCR/ABL-positive, not having achieved remission - Chronic myeloid leukemia, BCR/ABL-positive, in relapse |
| C93.10 - C93.12 | Chronic myelomonocytic leukemia not having achieved remission - Chronic myelomonocytic leukemia, in relapse |
| D48.1 | Neoplasm of uncertain behavior of connective and other soft tissue |

**Group 22 Paragraph:** CPT code 81332 (SERPINA1) is considered medically necessary for the following ICD-10-CM code:

**Group 22 Codes:**

| ICD-10 Codes | Description |
|---|---|
| E88.01 | Alpha-1-antitrypsin deficiency |

**Group 23 Paragraph:** CPT codes 81340 (TRB@, PCR), 81341 (TRB@ Southern blot), and 81342 (TRG@) are considered medically necessary for the following ICD-10-CM codes:

**Group 23 Codes:**

| ICD-10 Codes | Description |
|---|---|
| C91.00 - C91.02 | Acute lymphoblastic leukemia not having achieved remission - Acute lymphoblastic leukemia, in relapse |
| C95.90 - C95.92 | Leukemia, unspecified not having achieved remission - Leukemia, unspecified, in relapse |
| C96.2* | Malignant mast cell tumor |
| D60.0 | Chronic acquired pure red cell aplasia |
| D60.1 | Transient acquired pure red cell aplasia |
| D60.8 | Other acquired pure red cell aplasias |
| D61.01 | Constitutional (pure) red blood cell aplasia |
| D61.09 | Other constitutional aplastic anemia |
| D61.1 | Drug-induced aplastic anemia |
| D61.2 | Aplastic anemia due to other external agents |
| D61.3 | Idiopathic aplastic anemia |
| D61.89 | Other specified aplastic anemias and other bone marrow failure syndromes |
| D61.9 | Aplastic anemia, unspecified |

**Group 23 Medical Necessity ICD-10 Codes Asterisk Explanation:** C96.2 is applicable to CPT code 81342 only.

**Group 24 Paragraph:**
CPT code 81401 IGH@BCL2 (t(14:18)) is considered medically necessary for patients who have non- Hodgkin's lymphoma.

**Group 24 Codes:**

| ICD-10 Codes | Description |
|---|---|
| C85.10 - C85.99 | Unspecified B-cell lymphoma, unspecified site - Non-Hodgkin lymphoma, unspecified, extranodal and solid organ sites |

**Group 25 Paragraph:** CPT codes 81404 and 81405 (RET- Types 2B and 2A) are considered medically necessary for the following ICD-10-CM codes:

**Group 25 Codes:**

| ICD-10 Codes | Description |
|---|---|
| C73 | Malignant neoplasm of thyroid gland |
| C74.10 - C74.12 | Malignant neoplasm of medulla of unspecified adrenal gland - Malignant neoplasm of medulla of left adrenal gland |
| C75.0 | Malignant neoplasm of parathyroid gland |

| ICD-10 Codes | Description |
|---|---|
| D35.1 | Benign neoplasm of parathyroid gland |
| E83.01 | Wilson's disease |

**Group 26 Paragraph:** CPT code 81406 (ATP7B) is considered medically necessary for the following ICD-10-CM code:

**Group 26 Codes:**

| ICD-10 Codes | Description |
|---|---|
| E83.01 | Wilson's disease |

**Group 27 Paragraph:** CPT code 81519 (Oncology, breast mRNA) and CPT 0008M Prosigna® Breast Cancer Prognostic Gene Signature Assay are considered medically necessary for the following ICD-10-CM codes:

**Group 27 Codes:**

| ICD-10 Codes | Description |
|---|---|
| C50.011 | Malignant neoplasm of nipple and areola, right female breast |
| C50.012 | Malignant neoplasm of nipple and areola, left female breast |
| C50.019 | Malignant neoplasm of nipple and areola, unspecified female breast |
| C50.021 | Malignant neoplasm of nipple and areola, right male breast |
| C50.022 | Malignant neoplasm of nipple and areola, left male breast |
| C50.029 | Malignant neoplasm of nipple and areola, unspecified male breast |
| C50.111 | Malignant neoplasm of central portion of right female breast |
| C50.112 | Malignant neoplasm of central portion of left female breast |
| C50.119 | Malignant neoplasm of central portion of unspecified female breast |
| C50.121 | Malignant neoplasm of central portion of right male breast |
| C50.122 | Malignant neoplasm of central portion of left male breast |
| C50.129 | Malignant neoplasm of central portion of unspecified male breast |
| C50.211 | Malignant neoplasm of upper-inner quadrant of right female breast |
| C50.212 | Malignant neoplasm of upper-inner quadrant of left female breast |
| C50.219 | Malignant neoplasm of upper-inner quadrant of unspecified female breast |
| C50.221 | Malignant neoplasm of upper-inner quadrant of right male breast |
| C50.222 | Malignant neoplasm of upper-inner quadrant of left male breast |
| C50.229 | Malignant neoplasm of upper-inner quadrant of unspecified male breast |
| C50.311 | Malignant neoplasm of lower-inner quadrant of right female breast |
| C50.312 | Malignant neoplasm of lower-inner quadrant of left female breast |
| C50.319 | Malignant neoplasm of lower-inner quadrant of unspecified female breast |
| C50.321 | Malignant neoplasm of lower-inner quadrant of right male breast |
| C50.322 | Malignant neoplasm of lower-inner quadrant of left male breast |
| C50.329 | Malignant neoplasm of lower-inner quadrant of unspecified male breast |
| C50.411 | Malignant neoplasm of upper-outer quadrant of right female breast |
| C50.412 | Malignant neoplasm of upper-outer quadrant of left female breast |
| C50.419 | Malignant neoplasm of upper-outer quadrant of unspecified female breast |
| C50.421 | Malignant neoplasm of upper-outer quadrant of right male breast |
| C50.422 | Malignant neoplasm of upper-outer quadrant of left male breast |
| C50.429 | Malignant neoplasm of upper-outer quadrant of unspecified male breast |
| C50.511 | Malignant neoplasm of lower-outer quadrant of right female breast |
| C50.512 | Malignant neoplasm of lower-outer quadrant of left female breast |
| C50.519 | Malignant neoplasm of lower-outer quadrant of unspecified female breast |
| C50.521 | Malignant neoplasm of lower-outer quadrant of right male breast |
| C50.522 | Malignant neoplasm of lower-outer quadrant of left male breast |
| C50.529 | Malignant neoplasm of lower-outer quadrant of unspecified male breast |
| C50.611 | Malignant neoplasm of axillary tail of right female breast |
| C50.612 | Malignant neoplasm of axillary tail of left female breast |
| C50.619 | Malignant neoplasm of axillary tail of unspecified female breast |
| C50.621 | Malignant neoplasm of axillary tail of right male breast |
| C50.622 | Malignant neoplasm of axillary tail of left male breast |
| C50.629 | Malignant neoplasm of axillary tail of unspecified male breast |

| ICD-10 Codes | Description |
|---|---|
| C50.811 | Malignant neoplasm of overlapping sites of right female breast |
| C50.812 | Malignant neoplasm of overlapping sites of left female breast |
| C50.819 | Malignant neoplasm of overlapping sites of unspecified female breast |
| C50.821 | Malignant neoplasm of overlapping sites of right male breast |
| C50.822 | Malignant neoplasm of overlapping sites of left male breast |
| C50.829 | Malignant neoplasm of overlapping sites of unspecified male breast |
| C50.911 | Malignant neoplasm of unspecified site of right female breast |
| C50.912 | Malignant neoplasm of unspecified site of left female breast |
| C50.919 | Malignant neoplasm of unspecified site of unspecified female breast |
| C50.921 | Malignant neoplasm of unspecified site of right male breast |
| C50.922 | Malignant neoplasm of unspecified site of left male breast |
| C50.929 | Malignant neoplasm of unspecified site of unspecified male breast |
| D05.00 | Lobular carcinoma in situ of unspecified breast |
| D05.01 | Lobular carcinoma in situ of right breast |
| D05.02 | Lobular carcinoma in situ of left breast |
| D05.10 | Intraductal carcinoma in situ of unspecified breast |
| D05.11 | Intraductal carcinoma in situ of right breast |
| D05.12 | Intraductal carcinoma in situ of left breast |
| D05.80 | Other specified type of carcinoma in situ of unspecified breast |
| D05.81 | Other specified type of carcinoma in situ of right breast |
| D05.82 | Other specified type of carcinoma in situ of left breast |
| D05.90 | Unspecified type of carcinoma in situ of unspecified breast |
| D05.91 | Unspecified type of carcinoma in situ of right breast |
| D05.92 | Unspecified type of carcinoma in situ of left breast |
| Z17.0 | Estrogen receptor positive status [ER+] |

**Group 28 Paragraph:** CPT code 81595 Cardiology (heart transplant), mRNA is considered medically necessary for the following ICD-10-CM codes:

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**Group 28 Codes:**

| ICD-10 Codes | Description |
|---|---|
| Z48.21 | Encounter for aftercare following heart transplant |
| Z94.1 | Heart transplant status |

**Group 29 Paragraph:** CPT code 81310 NPM1 (nucleophosmin) is considered medically necessary for the following ICD-10-CM codes:

**Group 29 Codes:**

| ICD-10 Codes | Description |
|---|---|
| C92.00 | Acute myeloblastic leukemia, not having achieved remission |
| C92.02 | Acute myeloblastic leukemia, in relapse |
| C92.30 | Myeloid sarcoma, not having achieved remission |
| C92.32 | Myeloid sarcoma, in relapse |
| C92.40 | Acute promyelocytic leukemia, not having achieved remission |
| C92.42 | Acute promyelocytic leukemia, in relapse |
| C92.50 | Acute myelomonocytic leukemia, not having achieved remission |
| C92.52 | Acute myelomonocytic leukemia, in relapse |
| C92.60 | Acute myeloid leukemia with 11q23-abnormality not having achieved remission |
| C92.62 | Acute myeloid leukemia with 11q23-abnormality in relapse |
| C92.A0 | Acute myeloid leukemia with multilineage dysplasia, not having achieved remission |
| C92.A2 | Acute myeloid leukemia with multilineage dysplasia, in relapse |
| C92.Z0 | Other myeloid leukemia not having achieved remission |
| C92.Z2 | Other myeloid leukemia, in relapse |
| C94.00 | Acute erythroid leukemia, not having achieved remission |
| C94.02 | Acute erythroid leukemia, in relapse |

ICD-10 Codes that DO NOT Support Medical Necessity
**Group 1 Paragraph:** The following ICD-10-CM codes are considered non-covered for all molecular pathology procedures:

**Group 1 Codes:**

| ICD-10 Codes | Description |
|---|---|
| Z31.430 | Encounter of female for testing for genetic disease carrier status for procreative management |
| Z31.438 | Encounter for other genetic testing of female for procreative management |
| Z31.440 | Encounter of male for testing for genetic disease carrier status for procreative management |
| Z31.441 | Encounter for testing of male partner of patient with recurrent pregnancy loss |
| Z31.448 | Encounter for other genetic testing of male for procreative management |
| Z31.5 | Encounter for genetic counseling |

ICD-10 Additional Information

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# General Information

Associated Information
**Documentation Requirements**

Documentation must be adequate to verify that coverage guidelines listed above have been met. Thus, the medical record must contain documentation that the testing is expected to influence treatment of the condition toward which the testing is directed. The laboratory or billing provider must have on file the physician requisition which sets forth the diagnosis or condition (ICD-10-CM code) that warrants the test(s).

Examples of documentation requirements of the ordering physician/nonphysician practitioner (NPP) include, but are not limited to, history and physical or exam findings that support the decision making, problems/diagnoses, relevant data (e.g., lab testing, imaging results).

Documentation requirements of the performing laboratory (when requested) include, but are not limited to, lab accreditation, test requisition, test record/procedures, reports (preliminary and final), and quality control record.

Documentation requirements for LDT(s)/protocols (when requested) include diagnostic test/assay, lab/manufacturer, names of comparable assays/services (if relevant), description of assay, analytical validity evidence, clinical validity evidence, and clinical utility.

Providers are required to code to specificity however, if CPT 81479 (unlisted molecular pathology procedure) is used the documentation must clearly identify the unique molecular pathology procedure performed. When multiple procedure codes are submitted on a claim (unique and/or unlisted) the documentation supporting each code should be easily identifiable. If on review the contractor cannot link a billed code to the documentation, these services will be denied based on Title XVIII of the Social Security Act, §1833(e).

For these tests, the ordering provider must provide to the laboratory copies of the signed informed consent documentation.

An Advance Beneficiary Notice of Noncoverage (ABN) is required before furnishing a beneficiary a test which the physician or laboratory believes to be noncovered by Medicare as not reasonable or necessary. *The physician or laboratory must obtain a signed ABN from the beneficiary (or representative) that the physician or laboratory has informed him/her on the non-coverage of the test and that there will be a charge for the test.*

When the documentation does not meet the criteria for the service rendered or the documentation does not establish the medical necessity for the services, such services will be denied as not reasonable and necessary under Section 1862(a)(1)(A) of the Social Security Act.

**Utilization Guidelines**

Screening services such as pre-symptomatic genetic tests and services used to detect an undiagnosed disease or

disease predisposition are not a Medicare benefit and are not covered. Similarly, Medicare may not reimburse the costs of tests/examinations that assess the risk of a condition unless the risk assessment clearly and directly effects the management of the patient.

Title XVIII of the Social Security Act (SSA) §1862(a)(1)(A) states that no Medicare payment shall be made for items and services which are not reasonable and necessary for the diagnosis or treatment of illness or injury. Based on this statute, CMS states that *"tests that are performed in the absence of signs, symptoms, complaints, or personal history of disease or injury are non-covered unless explicitly authorized by statute."*

A specific genetic test may only be performed once in a lifetime per beneficiary for inherited conditions; however, when medically reasonable and necessary, genetic testing may be done on acquired conditions such as malignancies (including separate malignancies developing at different times) as they are treated and are being followed, in order to assess response or other relevant clinical criteria. Likewise, there are situations where medical record and literature documentation are able to demonstrate that serial testing can be reasonably predicted to provide additional clinically useful information. When the record documents that this information, such as confirmed significant response to current therapy, is likely to assist in modifying treatment, serial testing can be considered reasonable and necessary and eligible for coverage.

**Appendices**
N/A

Sources of Information and Basis for Decision
Agency for Healthcare Research and Quality (AHRQ). Update for horizon scans of genetic tests currently available for clinical use in cancers. 2011. Tufts Evidence-based Practice Center.

American Medical Association. Current procedural terminology (CPT®) professional edition 2013.

Centers for Disease Control and Prevention (CDC). Genomic testing: Genomic tests by level of evidence. 2013. http://www.cdc.gov/genomics/gtesting/

Current Procedural Terminology (CPT), 2015 American Medical Association.

Hampel H, Frankel WL, Martin E, Arnold, et al. Screening for the lynch syndrome (hereditary nonpolyposis colorectal cancer). *New England Journal of Medicine.* 2005;352(18):1851-60.

LCDs and policies from other Medicare contractors and private insurers

Loupakis, F., et al, KRAS codon 61, 146, and BRAF mutations predict resistance to cetuximab and irinotecan in KRAS codon 12 and 13, wild type metastatic colorectal cancer. BR J Cancer, 2009. 101(4): p. 715-721.

Schmeler KM, Lynch HT, Chen L, et al. Prophylactic surgery to reduce the risk of gynecologic cancers in lynch syndrome. *New England Journal of Medicine.* 2006;354(3):261-269.

Secretary's Advisory Committee on Genetics, Health, and Society. U.S. system of oversight of genetic testing: A response to the charge of the secretary of health and human services. *Department of Health and Human Services.* 2008. http://www4.od.nih.gov/oba/sacghs/reports/SACGHS_oversight_report.pdf

U.S. Preventive Services Task Force. Genetic risk assessment and BRCA mutation testing for breast and ovarian cancer susceptibility: Recommendation statement. 2005. http://www.uspreventiveservicestaskforce.org/uspstf05/brcagen/brcagenrs.htm.

Vaughn, C.P., et al, Frequency of KRAS, BRAF, and NRAS Mutations in Colorectal Cancer. Genes, Chromosomes, and Cancer, 2011, 501(5): p. 307-312.

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# Revision History Information

| Revision History Date | Revision History Number | Revision History Explanation | Reason(s) for Change |
|---|---|---|---|
| 02/01/2017 | R8 | | • Provider Education/Guidance |

| Revision History Date | Revision History Number | Revision History Explanation | Reason(s) for Change |
|---|---|---|---|
| 01/01/2017 | R7 | CPT code 81450 was removed from CPT/HCPCS NON-COVERED MOLECULAR PATHOLOGY PROCEDURES -Group 3. Refer to LCD L36926 Genomic Sequence Analysis Panels in the Treatment of Acute Myelogenous Leukemia (AML), effective for services rendered on or after 2/1/2017.<br>The following revisions are effective for services rendered on or after 1/1/2017:<br>**CPT codes 81280, 81281, 81282, 81413, and 81414**<br>CPT codes 81280, 81281, and 81282 will be deleted as of 12/31/2016. The genes addressed by CPT codes 81280-81282 are now included in new CPT codes 81413 and 81414. CPT codes 81413 and 81314 also include genes which would have been reported with Tier 2 molecular CPT codes or CPT code 81479 which were considered not medically necessary. Codes 81413 and 81314 will be added to Group 3- NON-COVERED MOLECULAR PATHOLOGY PROCEDURES, effective for services rendered on or after 1/1/2017. No change in coverage.<br><br>**CPT Code 81422**<br>Added new CPT code 81422 to Group 3- NON-COVERED MOLECULAR PATHOLOGY PROCEDURES, effective 1/1/2017. For dates of service prior to 12/31/2016, Tier 2 molecular CPT codes or CPT code 81479 would have been used to report the genes included in this code which were considered not medically necessary. No change in coverage.<br><br>**CPT Code 81439**<br>Added new CPT code 81439 to Group 3- NON-COVERED MOLECULAR PATHOLOGY PROCEDURES. For dates of service prior to 12/31/2016, Tier 2 molecular CPT codes or CPT code 81479 would have been used to report the genes included in this code which were considered not medically necessary. No change in coverage.<br><br>**CPT Code 81218**<br>Added the following additional ICD-10-CM codes to the ICD-10 Codes that Support Medical Necessity section, Group 5: C92.00, C92.30, C92.02, C92.32, C92.40, C92.42, C92.50, C92.52, C92.A0, C92.A2, C92.Z0, C94.00, C94.02, C92.Z2. Removed ICD-10-CM codes C91.00-C91.02 that had been added previously in error. The ICD-10-CM diagnosis codes now align with the Indications of Coverage for Acute Myelogenous Leukemia (AML).<br><br>**CPT Codes 81245, 81246**<br>Added the following additional ICD-10-CM codes to the ICD-10 Codes that Support Medical Necessity section, Group 12: C92.30, C92.32, C94.00, C94.02, C92.Z0, C92.Z2, C92.A0, C92.A2. Removed the following ICD-10-CM codes to the ICD-10 Codes that Support Medical Necessity section, Group 12: C92.01, C92.41, C92.51, C92.61.<br><br>**CPT Codes 81261-81264**<br>Corrected the ICD-10 Codes that Support Medical Necessity section, Group 14 to align with the Indications of Coverage by removing the incorrect ranges (C91.00-C91.32, C91.50-C91.62, C91.A0-C93.92) and adding the following specific ICD-10-CM codes to Group 14 : C92.00, C92.02, C92.30, C92.32, C92.40, C92.42, C92.50, C92.52, C92.60, C92.62, C92.A0, C92.A2, C92.Z0, C92.Z2, C94.00, and C94.02.<br><br>**CPT Code 81272** | • Revisions Due To CPT/HCPCS Code Changes |

| Revision History Date | Revision History Number | Revision History Explanation | Reason(s) for Change |
|---|---|---|---|
| | | Added the following additional ICD-10-CM codes to the ICD-10 Codes that Support Medical Necessity section, Group 16: C92.30, C92.32, C92.Z0, C92.Z2, C92.60, C92.62, C92.A0, C92.A2, and C94.00, C94.02<br><br>**CPT Code 81310**<br>Added a new ICD-10-CM to CPT code Group 29 to align with the Indications of Coverage for Acute Myelogenous Leukemia (AML). Added the following additional ICD-10-CM codes to the ICD-10 Codes that Support Medical Necessity section, Group 29: C92.00, C92.02, C92.30, C92.32, C92.40, C92.42, C92.50, C92.52, C92.60, C92.62, C92.A0, C92.A2, C92.Z0, C92.Z2, C94.00, and C94.02.<br><br>The following revisions, not listed in prior Revision History # 6, are effective for services rendered on or after 12/1/2016:<br>**CPT Code 81210**<br>Added the following additional ICD-10-CM codes to the ICD-10 Codes that Support Medical Necessity section, Group 4: C17.0-C17.9, C18.0-C19, C20, C21.1-C21.8, C78.4, C78.5, Z85.038, Z85.048<br><br>**CPT 81219**<br>Removed CPT code 81219 (CALR) in the ICD-10 Codes that Support Medical Necessity section, Group 15.<br><br>**CPT 81287**<br>Added the following ICD-10-CM codes to the ICD-10 Codes that Support Medical Necessity section, Group 18: C71.0 - C71.9<br><br>**CPT code 81301**<br>Added the following ICD-10-CM codes to theICD-10 Codes that Support Medical Necessity section Group 19: C17.0 -C17.9, C18.0-C18.9, C19, C20, C21.1-C21.8, C33, C34.00-C34.12, C34.2, C34.30-C34.32, C34.80-C34.82, C34.90-C34.92, Z85.038, Z85.048<br><br>**CPT 81332**<br>Added the following ICD-10-CM code to the ICD-10 Codes that Support Medical Necessity section Group 22: E88.01<br><br>**CPT code 81340, 81341, 81342**<br>Added the following ICD-10-CM codes to the ICD-10 Codes that Support Medical Necessity section Group 23: C91.00-C91.02, C95.90-C95.92, D60.0, D60.1, D60.8, D61.01, D61.09, D61.1-D61.3, D61.89, D61.9 | |
| 12/01/2016 | R6 | Consolidated Molecular Pathology Procedures into three (3) separate CPT/HCPCS section Groups: Group 1- COVERED MOLECULAR PATHOLOGY PROCEDURES, GROUP-2 MOLECULAR PATHOLOGY PROCEDURES THAT REQUIRE INDIVIDUAL REVIEW, and GROUP 3-NON-COVERED MOLECULAR PATHOLOGY PROCEDURES<br><br>**CPT Codes 81162, 81211, 81212, 81213, 81214, 81215, 81216, 81217 (BRCA1 and BRCA2)** | • Provider Education/Guidance |

| Revision History Date | Revision History Number | Revision History Explanation | Reason(s) for Change |
|---|---|---|---|

Removed CPT/HCPCS Codes from Group 2, TIER 1 AND TIER 2 MOLECULAR PATHOLOGY PROCEDURES THAT REQUIRE INDIVIDUAL REVIEW and added to CPT/HCPCS Codes section, GROUP 1- COVERED MOLECULAR PATHOLOGY PROCEDURES. Added ICD-10-CM diagnosis codes Z86.000 and Z85.3 as payable for these CPT codes.

**CPT code 81170 (ABL1)**
Revised the Indications of Coverage section by removing the typographical error "chronic lymphoblastic leukemia (CLL)" and replacing with "chronic myeloid leukemia (CML)". Revised the ICD-10 Codes that Support Medical Necessity section, Group 2, by removing the typographical error and replacing ICD-10-CM diagnosis code ranges C91.00-C91.02 and C91.10-C91.12 with ICD-10-CM diagnosis code ranges C92.10-C92.12 and C92.20-C92.22.

**CPT code 81209 (BLM (Bloom syndrome, RecQ helicase-like)**
Removed CPT code from TIER 1 NON-COVERED MOLECULAR PATHOLOGY PROCEDURES, Group 3, and added to CPT/HCPCS Codes section, GROUP 1- COVERED MOLECULAR PATHOLOGY PROCEDURES, Group1. Added criteria to the Indications and Limitations of Coverage section.

**CPT Codes 81220, 81221, 81222, 81223, 81224 (CFTR)**
Removed CPT codes from CPT/HCPCS Codes section, TIER 1 NON-COVERED MOLECULAR PATHOLOGY PROCEDURES, Group 3, and added to CPT/HCPCS Codes section, GROUP 1- COVERED MOLECULAR PATHOLOGY PROCEDURES. Added criteria to Indications and Limitations of Coverage section.

**CPT code 81272 (KIT)**
Added 2017 ICD-10-CM diagnosis code range C49.A0-C49.A9 to the ICD-10 Codes that Support Medical Necessity section, Group 16.

**CPT code 81313 (PCA3)**
Removed 81313 from CPT/HCPCS Codes section, Group 2, TIER 1 AND TIER 2 MOLECULAR PATHOLOGY PROCEDURES THAT REQUIRE INDIVIDUAL REVIEW and added to CPT/HCPCS Codes section, GROUP 1- COVERED MOLECULAR PATHOLOGY PROCEDURES. Added ICD-10-CM diagnosis code R97.2 to ICD-10 Codes that Support Medical Necessity section, Group 7.

**CPT Codes 81315, 81316 (PML/RARALPHA, (T(15;17)))**
Removed CPT codes from CPT/HCPCS Codes section, Group 2, TIER 1 AND TIER 2 MOLECULAR PATHOLOGY PROCEDURES THAT REQUIRE INDIVIDUAL REVIEW, and added to CPT/HCPCS Codes section, GROUP 1-COVERED MOLECULAR PATHOLOGY PROCEDURES. Added ICD-10 Code range C92.40-C92.42 Acute promyelocytic leukemia to ICD-10 Codes that Support Medical Necessity section, Group 8.

**CPT code 81401 (CBFB-MYH11)**
Corrected name of gene 81401 CYFB-MYH11 to CBFB-MYH11 in COVERED MOLECULAR PATHOLOGY PROCEDURES section.

**CPT code 81519 (ONCOLOGY (BREAST), MRNA)**
Removed CPT code 81519 from Group 7, COVERED MULTIANALYTE ASSAYS with ALGORITHMIC ANALYSES PROCEDURES and added to CPT/HCPCS Codes section, GROUP 1- COVERED MOLECULAR PATHOLOGY PROCEDURES.

| Revision History Date | Revision History Number | Revision History Explanation | Reason(s) for Change |
|---|---|---|---|
| | | **CPT code 81595 (CARDIOLOGY (HEART TRANSPLANT), MRNA,)**<br>Removed CPT code 81595 from Group 7, COVERED MULTIANALYTE ASSAYS with ALGORITHMIC ANALYSES PROCEDURES and added to CPT/HCPCS Codes section, GROUP 1- COVERED MOLECULAR PATHOLOGY PROCEDURES.<br><br>**CPT code 81599 UNLISTED MULTIANALYTE ASSAY WITH ALGORITHMIC ANALYSIS**<br>Removed CPT code from Group 6- MULTIANALYTE ASSAYS with ALGORITHMIC ANALYSES PROCEDURES THAT REQUIRE INDIVIDUAL REVIEW and added CPT code 81599 to GROUP 2- MOLECULAR PATHOLOGY PROCEDURES THAT REQUIRE INDIVIDUAL REVIEW<br><br>**CPT code 0008M (Prosigna® Breast Cancer Prognostic Gene Signature Assay)**<br>Added criteria to Indications and Limitations of Coverage section. Removed CPT code 0008M from NON-COVERED GENOMIC SEQUENCING PROCEDURES AND OTHER MULTIANALYTE ASSAYS WITH ALGORITHMIC ANALYSES PROCEDURES, Group 5 and added CPT code 0008M to GROUP 1 - COVERED MOLECULAR PATHOLOGY PROCEDURES. Added CPT code 0008M to the ICD-10 Codes that Support Medical Necessity section, Group 27. | |
| 10/01/2016 | R5 | Added ICD-10-CM diagnosis code range C49.A0-C49.A9 to the ICD-10 Codes that Support Medical Necessity section that relates to CPT code 81272 (Group 12). | • Revisions Due To ICD-10-CM Code Changes |
| 04/01/2016 | R4 | The LCD has been revised during the notice period to remove codes 81442, 81490-81595 from Group 5 CPT Code section and to delete Group 6 CPT Code section (NON-COVERED ADMINISTRATIVE CODES FOR MULTIANALYTE ASSAYS WITH ALGORITHMIC ANALYSES (MAAA) that contained codes 0001M-0004M and 0006M-0010M. | • Other (The CPT codes were not included in DL35000.) |
| 04/01/2016 | R3 | Added the following CPT codes and indications and limitations of coverage to the **TIER 1 AND TIER 2 INDICATIONS AND LIMITATIONS OF COVERAGE** section: 81170, 81162, 81216, 81218, 81219, 81227, 81245, 81246, 81271, 81273, 81276, 81301, 81311, 81314, 81370-81383, 81401, 81404, 81405, 81406<br><br>Added the following CPT codes to the CPT HCPCS Group 1 **TIER 1 COVERED MOLECULAR PATHOLOGY PROCEDURES** section: 81170, 81218, 81225, 81272, 81273, 81276, 81310, 81311, 81314, 81370-81383<br><br>Added the following CPT codes to the CPT HCPCS Group 2 **TIER 1 AND TIER 2 MOLECULAR PATHOLOGY PROCEDURES THAT REQUIRE INDIVIDUAL REVIEW** section: 81162, 81216, 81301<br><br>Added the following CPT codes to the CPT HCPCS Group 3 **TIER 1 NON-COVERED MOLECULAR PATHOLOGY PROCEDURES** section: 81219, 81227, 81355 | • Provider Education/Guidance<br>• Revisions Due To CPT/HCPCS Code Changes |

| Revision History Date | Revision History Number | Revision History Explanation | Reason(s) for Change |
|---|---|---|---|
| | | Added the following CPT codes to the CPT HCPCS Group 5 **NON-COVERED GENOMIC SEQUENCING PROCEDURES AND MULTIANALYTE ASSAYS WITH ALGORITHMIC ANALYSES (MAAA)** section: 81442, 81490, 81493, 81500-81507, 81525, 81535, 81538, 81540, 81595<br><br>Added CPT code and ICD-10-CM diagnosis code groupings in **ICD-10-CM Diagnosis Codes that Support Medical Necessity** section for the following CPT codes: 81170, 81218, 81245-81246, 81272-81273, 81275-81276, 81311, 81314, 81401, 81404, 81405, 81406<br><br>Added the following CPT code ranges to the CPT HCPCS Group 6 NON-COVERED ADMINISTRATIVE MULTIANALYTE ASSAYS WITH ALGORITHMIC ANALYSES (MAAA) section: 0001M-0004M, 0006M-0010M<br><br>Added the following language to bullet number 6 in the Indications of Coverage section: "Exceptions include clinical scenarios whereby repeat testing of somatically-acquired mutations (for example, pre- and post- therapy) may be required to inform appropriate therapeutic decision-making.” | |
| 01/01/2016 | R2 | Based on the CPT/HCPCS annual update, the descriptions for the following codes have been changed: 81210, 81275, 81355, 81402. | • Revisions Due To CPT/HCPCS Code Changes |
| 10/01/2015 | R1 | LCD updated to reflect administrative changes. | • Provider Education/Guidance |

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# Associated Documents

Attachments N/A

Related Local Coverage Documents Article(s) A55334 - Response to Comments: Molecular Pathology Procedures

Related National Coverage Documents N/A

Public Version(s) Updated on 01/20/2017 with effective dates 02/01/2017 - N/A Updated on 12/21/2016 with effective dates 01/01/2017 - 01/31/2017 Updated on 10/07/2016 with effective dates 12/01/2016 - 12/31/2016 Updated on 09/22/2016 with effective dates 10/01/2016 - 11/30/2016 Updated on 02/26/2016 with effective dates 04/01/2016 - 09/30/2016 Updated on 02/04/2016 with effective dates 04/01/2016 - N/A Updated on 12/24/2015 with effective dates 01/01/2016 - 03/31/2016 Some older versions have been archived. Please visit the MCD Archive Site to retrieve them. Back to Top

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