Article - Billing and Coding: Molecular Pathology Procedures (A56199)

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Contractor Information

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATES
National Government Services, Inc.	MAC - Part A	06101 - MAC A	J - 06	Illinois
National Government Services, Inc.	MAC - Part B	06102 - MAC B	J - 06	Illinois
National Government Services, Inc.	MAC - Part A	06201 - MAC A	J - 06	Minnesota
National Government Services, Inc.	MAC - Part B	06202 - MAC B	J - 06	Minnesota
National Government Services, Inc.	MAC - Part A	06301 - MAC A	J - 06	Wisconsin
National Government Services, Inc.	MAC - Part B	06302 - MAC B	J - 06	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,	A and B and HHH	14212 - MAC B	J - K	Massachusetts

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATES
Inc.	MAC			
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

Article Information

General Information

Article ID
A56199

Article Title
Billing and Coding: Molecular Pathology Procedures

Article Type
Billing and Coding

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N/A

AMA CPT / ADA CDT / AHA NUBC Copyright Statement

CMS National Coverage Policy

N/A

Article Guidance

Article Text

This article contains coding and other guidelines that complement the Local Coverage Determination (LCD) for Molecular Pathology Procedures.

Specific Coding of Molecular Testing Panels

The submission of claims using individual gene CPT codes, when either 5-50 or >50 gene panels are ordered, is considered incorrect coding. Correct coding requires that when a panel code is ordered, it should be billed, rather than the individual gene codes. CPT code 81445 or 81450 should be billed when 5 to 50 genes are ordered. CPT code 81455 should be billed when 51 or greater genes are ordered for molecular biomarkers. Please refer to Local Coverage Determination L37810 Genomic Sequence Analysis Panels in the Treatment of Solid Organ Neoplasms and the associated Article A56867. When a panel with greater than one or less than five genes is ordered, use the corresponding existing panel CPT code or CPT code 81479 if none exists.

Coding Information:

Coding guidance in this article is categorized into four, distinct CPT/HCPCS sections:

· CPT/HCPCS section-Group1-Tier 1 Covered Codes for which limited coverage may be provided for the genetic tests and for which specific ICD-10-CM diagnosis to CPT procedure groupings may be listed

· CPT/ HCPCS section-Group 2-Tier 1 Codes that require Individual Review for which coverage may be provided for the genetic tests submitted, if documentation supports medical necessity, and for which specific ICD-10-CM diagnosis to CPT procedure groupings may be listed.

Article Text

· CPT/HCPCS section-Group 3-Tier 1 Non-covered Codes for which genetic testing is unlikely to impact therapeutic decision-making in the clinical management of the patient and will be denied automatically as not medically necessary.

· CPT/HCPCS section-Group 4- Tier 2/NOC Covered Code/Gene Combinations for which limited coverage may be provided for specific genes listed in the Group 4 paragraph; Tier 2/NOC Individual Review Code/Gene Combinations; Tier 2/NOC Non-covered Code/Gene Combinations.

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 Not Otherwise Classified (NOC) CPT code 81479 is required.

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.

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.

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 indicated in patients with suspected CML with either persistent, unexplained leukocytosis or thrombocytosis. 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 81162-81367, 81212, 81215, 81216, 81217 BRCA1 and BRCA2 genetic testing is considered medically necessary for a beneficiary with a current diagnosis or 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, and the results will be used to benefit the individual tested in terms of potential to guide therapeutic decision making.

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.

Use CPT code 81227 for CYP2C9 genotyping for individuals who have a relapsing form of multiple sclerosis, and require CYP2C9 genotyping for dosing in accordance with the FDA prescribing information for Mayzent. CYP2C9 testing must include the *1, *2, and *3 alleles that are necessary

to safely dose the FDA-approved drug Mayzent.

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 lymphoblastic leukemia (ALL) 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 myeloproliferative neoplasm (MPN) (polycythemia vera (PV), essential thrombocythemia (ET) or primary myelofibrosis (PMF)) or a myelodysplastic syndrome (MDS). Note: JAK2 (exons 12 and 13) (reported with 81403) is medically necessary in 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.

MSI testing is also required by FDA for the clinical use of Keytruda (pembrolizumab) in a restricted population of patients. These are patients who have unresectable or metastatic solid tumors who have progressed following prior treatment and have no satisfactory alternative options. When Keytruda (pembrolizumab) is a potential clinically appropriate therapeutic choice, MSI testing is medically necessary in these patients. Because this is a wide-ranging population of advanced cancer patients, ICD-10 specificity is impractical, therefore use an ICD-10 appropriate for the tumor type and location.

CPT Code 81305 MYD88 genetic test is considered medically necessary in patients with Marginal Zone Lymphoma (MZL), Waldenstrom’s Macroglobulinemia (WM) and Lymphoplasmacytic Lymphoma (LPL) to guide therapeutic decision-making.

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 81168 CCND1/IGH **81278** (BCL1/IgH, t)(eg, mantle cell lymphoma) translocation analysis, major breakpoint, qualitative and quantitative, if performed is considered medical necessary for patients who have non- Hodgkin's lymphoma to guide therapeutic decision-making.

CPT Code 81338 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 81339 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 Codes 81279 JAK2 (Janus kinase 2) (eg, myeloproliferative disorder), (exon 12 sequence and exon 13 sequence) and **0027U** (Janus kinase 2) (e.g., myeloproliferative disorder), gene analysis, targeted sequence analysis exons 12-15 are 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, 81351, 81352, 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 81404 MEN1 (multiple endocrine neoplasia 1) (eg, multiple endocrine neoplasia type 1, Wermer syndrome), duplication/deletion and CPT code 81405 MEN1 (multiple endocrine neoplasia 1) e.g. multiple endocrine neoplasia type 1, Wermer syndrome), duplication/deletion analysis) are considered medically necessary in patients with multiple endocrine neoplasia to guide therapeutic decision-making.

CPT codes 81352 TP53 (tumor protein 53) (e.g. tumor samples), targeted sequence analysis of 2-5 exons, and CPT code 81351 TP53 (tumor protein 53) (e.g. Li-Fraumeni syndrome, tumor samples), full gene sequence or targeted sequence analysis of >5 exons are considered medically necessary in individuals who have Acute Myelogenous Leukemia or Myeloplastic Disease 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 L37810).

CPT code 81479 and 81347 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. **81347** RARS (SF3B1 mutation) is considered medically necessary in patients with Myelodysplastic Syndrome to guide therapeutic decision-making.

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 81520 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

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.

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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.

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.

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.

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.

Coding Information

CPT/HCPCS Codes

Group 1 Paragraph:

Tier 1 Covered Codes

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

Please refer to the Indications and Limitations of Coverage section (L35000) and the ICD-10-CM diagnosis to CPT procedure groupings below.

Group 1 Codes: (98 Codes)

CODE	DESCRIPTION
81120	IDH1 (ISOCITRATE DEHYDROGENASE 1 [NADP+], SOLUBLE) (EG, GLIOMA), COMMON VARIANTS (EG, R132H, R132C)
81121	IDH2 (ISOCITRATE DEHYDROGENASE 2 [NADP+], MITOCHONDRIAL) (EG, GLIOMA), COMMON VARIANTS (EG, R140W, R172M)
81162	BRCA1 (BRCA1, DNA REPAIR ASSOCIATED), BRCA2 (BRCA2, DNA REPAIR ASSOCIATED) (EG, HEREDITARY BREAST AND OVARIAN CANCER) GENE ANALYSIS; FULL SEQUENCE ANALYSIS AND FULL DUPLICATION/DELETION ANALYSIS (IE, DETECTION OF LARGE GENE REARRANGEMENTS)
81163	BRCA1 (BRCA1, DNA REPAIR ASSOCIATED), BRCA2 (BRCA2, DNA REPAIR ASSOCIATED) (EG, HEREDITARY BREAST AND OVARIAN CANCER) GENE ANALYSIS; FULL SEQUENCE ANALYSIS
81164	BRCA1 (BRCA1, DNA REPAIR ASSOCIATED), BRCA2 (BRCA2, DNA REPAIR ASSOCIATED) (EG, HEREDITARY BREAST AND OVARIAN CANCER) GENE ANALYSIS; FULL DUPLICATION/DELETION ANALYSIS (IE, DETECTION OF LARGE GENE REARRANGEMENTS)
81165	BRCA1 (BRCA1, DNA REPAIR ASSOCIATED) (EG, HEREDITARY BREAST AND OVARIAN CANCER) GENE ANALYSIS; FULL SEQUENCE ANALYSIS
81166	BRCA1 (BRCA1, DNA REPAIR ASSOCIATED) (EG, HEREDITARY BREAST AND OVARIAN CANCER) GENE ANALYSIS; FULL DUPLICATION/DELETION ANALYSIS (IE, DETECTION OF LARGE GENE REARRANGEMENTS)
81167	BRCA2 (BRCA2, DNA REPAIR ASSOCIATED) (EG, HEREDITARY BREAST AND OVARIAN CANCER) GENE ANALYSIS; FULL DUPLICATION/DELETION ANALYSIS (IE, DETECTION OF LARGE GENE REARRANGEMENTS)

CODE	DESCRIPTION
81168	CCND1/IGH (T(11;14)) (EG, MANTLE CELL LYMPHOMA) TRANSLOCATION ANALYSIS, MAJOR BREAKPOINT, QUALITATIVE AND QUANTITATIVE, IF PERFORMED
81170	ABL1 (ABL PROTO-ONCOGENE 1, NON-RECEPTOR TYROSINE KINASE) (EG, ACQUIRED IMATINIB TYROSINE KINASE INHIBITOR RESISTANCE), GENE ANALYSIS, VARIANTS IN THE KINASE DOMAIN
81175	ASXL1 (ADDITIONAL SEX COMBS LIKE 1, TRANSCRIPTIONAL REGULATOR) (EG, MYELODYSPLASTIC SYNDROME, MYELOPROLIFERATIVE NEOPLASMS, CHRONIC MYELOMONOCYTIC LEUKEMIA), GENE ANALYSIS; FULL GENE SEQUENCE
81176	ASXL1 (ADDITIONAL SEX COMBS LIKE 1, TRANSCRIPTIONAL REGULATOR) (EG, MYELODYSPLASTIC SYNDROME, MYELOPROLIFERATIVE NEOPLASMS, CHRONIC MYELOMONOCYTIC LEUKEMIA), GENE ANALYSIS; TARGETED SEQUENCE ANALYSIS (EG, EXON 12)
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)
81212	BRCA1 (BRCA1, DNA REPAIR ASSOCIATED), BRCA2 (BRCA2, DNA REPAIR ASSOCIATED) (EG, HEREDITARY BREAST AND OVARIAN CANCER) GENE ANALYSIS; 185DELAG, 5385INSC, 6174DELT VARIANTS
81215	BRCA1 (BRCA1, DNA REPAIR ASSOCIATED) (EG, HEREDITARY BREAST AND OVARIAN CANCER) GENE ANALYSIS; KNOWN FAMILIAL VARIANT
81216	BRCA2 (BRCA2, DNA REPAIR ASSOCIATED) (EG, HEREDITARY BREAST AND OVARIAN CANCER) GENE ANALYSIS; FULL SEQUENCE ANALYSIS
81217	BRCA2 (BRCA2, DNA REPAIR ASSOCIATED) (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)

CODE	DESCRIPTION
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)
81227	CYP2C9 (CYTOCHROME P450, FAMILY 2, SUBFAMILY C, POLYPEPTIDE 9) (EG, DRUG METABOLISM), GENE ANALYSIS, COMMON VARIANTS (EG, *2, *3, *5, *6)
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)
81236	EZH2 (ENHANCER OF ZESTE 2 POLYCOMB REPRESSIVE COMPLEX 2 SUBUNIT) (EG, MYELODYSPLASTIC SYNDROME, MYELOPROLIFERATIVE NEOPLASMS) GENE ANALYSIS, FULL GENE SEQUENCE
81237	EZH2 (ENHANCER OF ZESTE 2 POLYCOMB REPRESSIVE COMPLEX 2 SUBUNIT) (EG, DIFFUSE LARGE B-CELL LYMPHOMA) GENE ANALYSIS, COMMON VARIANT(S) (EG, CODON 646)
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)

CODE	DESCRIPTION
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) PROMOTER 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

CODE	DESCRIPTION
	NORMAL TISSUE, IF PERFORMED
81305	MYD88 (MYELOID DIFFERENTIATION PRIMARY RESPONSE 88) (EG, WALDENSTROM'S MACROGLOBULINEMIA, LYMPHOPLASMACYTIC LEUKEMIA) GENE ANALYSIS, P.LEU265PRO (L265P) VARIANT
81307	PALB2 (PARTNER AND LOCALIZER OF BRCA2) (EG, BREAST AND PANCREATIC CANCER) GENE ANALYSIS; FULL GENE SEQUENCE
81308	PALB2 (PARTNER AND LOCALIZER OF BRCA2) (EG, BREAST AND PANCREATIC CANCER) GENE ANALYSIS; KNOWN FAMILIAL VARIANT
81309	PIK3CA (PHOSPHATIDYLINOSITOL-4, 5-BIPHOSPHATE 3-KINASE, CATALYTIC SUBUNIT ALPHA) (EG, COLORECTAL AND BREAST CANCER) GENE ANALYSIS, TARGETED SEQUENCE ANALYSIS (EG, EXONS 7, 9, 20)
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)
81334	RUNX1 (RUNT RELATED TRANSCRIPTION FACTOR 1) (EG, ACUTE MYELOID LEUKEMIA, FAMILIAL PLATELET DISORDER WITH ASSOCIATED MYELOID MALIGNANCY) GENE ANALYSIS, TARGETED SEQUENCE ANALYSIS (EG, EXONS 3-8)
81335	TPMT (THIOPURINE S-METHYLTRANSFERASE) (EG, DRUG METABOLISM), GENE ANALYSIS, COMMON VARIANTS (EG, *2, *3)
81338	MPL (MPL PROTO-ONCOGENE, THROMBOPOIETIN RECEPTOR) (EG,

CODE	DESCRIPTION
	MYELOPROLIFERATIVE DISORDER) GENE ANALYSIS; COMMON VARIANTS (EG, W515A, W515K, W515L, W515R)
81339	MPL (MPL PROTO-ONCOGENE, THROMBOPOIETIN RECEPTOR) (EG, MYELOPROLIFERATIVE DISORDER) GENE ANALYSIS; SEQUENCE ANALYSIS, EXON 10
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)
81345	TERT (TELOMERASE REVERSE TRANSCRIPTASE) (EG, THYROID CARCINOMA, GLIOBLASTOMA MULTIFORME) GENE ANALYSIS, TARGETED SEQUENCE ANALYSIS (EG, PROMOTER REGION)
81347	SF3B1 (SPLICING FACTOR [3B] SUBUNIT B1) (EG, MYELODYSPLASTIC SYNDROME/ACUTE MYELOID LEUKEMIA) GENE ANALYSIS, COMMON VARIANTS (EG, A672T, E622D, L833F, R625C, R625L)
81348	SRSF2 (SERINE AND ARGININE-RICH SPLICING FACTOR 2) (EG, MYELODYSPLASTIC SYNDROME, ACUTE MYELOID LEUKEMIA) GENE ANALYSIS, COMMON VARIANTS (EG, P95H, P95L)
81351	TP53 (TUMOR PROTEIN 53) (EG, LI-FRAUMENI SYNDROME) GENE ANALYSIS; FULL GENE SEQUENCE
81352	TP53 (TUMOR PROTEIN 53) (EG, LI-FRAUMENI SYNDROME) GENE ANALYSIS; TARGETED SEQUENCE ANALYSIS (EG, 4 ONCOLOGY)
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-

CODE	DESCRIPTION
	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
81518	ONCOLOGY (BREAST), MRNA, GENE EXPRESSION PROFILING BY REAL-TIME RT-PCR OF 11 GENES (7 CONTENT AND 4 HOUSEKEEPING), UTILIZING FORMALIN-FIXED PARAFFIN-EMBEDDED TISSUE, ALGORITHMS REPORTED AS PERCENTAGE RISK FOR METASTATIC RECURRENCE AND LIKELIHOOD OF BENEFIT FROM EXTENDED ENDOCRINE THERAPY
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
81520	ONCOLOGY (BREAST), MRNA GENE EXPRESSION PROFILING BY HYBRID CAPTURE OF 58 GENES (50 CONTENT AND 8 HOUSEKEEPING), UTILIZING FORMALIN-FIXED PARAFFIN-EMBEDDED TISSUE, ALGORITHM REPORTED AS A RECURRENCE RISK SCORE
81522	ONCOLOGY (BREAST), MRNA, GENE EXPRESSION PROFILING BY RT-PCR OF 12 GENES (8 CONTENT AND 4 HOUSEKEEPING), UTILIZING FORMALIN-FIXED PARAFFIN-EMBEDDED TISSUE, ALGORITHM REPORTED AS RECURRENCE RISK SCORE
81523	ONCOLOGY (BREAST), MRNA, NEXT-GENERATION SEQUENCING GENE EXPRESSION PROFILING OF 70 CONTENT GENES AND 31 HOUSEKEEPING GENES, UTILIZING FORMALIN-FIXED PARAFFIN-EMBEDDED TISSUE, ALGORITHM REPORTED AS INDEX RELATED TO RISK TO DISTANT METASTASIS
81552	ONCOLOGY (UVEAL MELANOMA), MRNA, GENE EXPRESSION PROFILING BY REAL-TIME RT-PCR OF 15 GENES (12 CONTENT AND 3 HOUSEKEEPING), UTILIZING FINE

CODE	DESCRIPTION
	NEEDLE ASPIRATE OR FORMALIN-FIXED PARAFFIN-EMBEDDED TISSUE, ALGORITHM REPORTED AS RISK OF METASTASIS
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
0027U	JAK2 (JANUS KINASE 2) (EG, MYELOPROLIFERATIVE DISORDER) GENE ANALYSIS, TARGETED SEQUENCE ANALYSIS EXONS 12-15
0070U	CYP2D6 (CYTOCHROME P450, FAMILY 2, SUBFAMILY D, POLYPEPTIDE 6) (EG, DRUG METABOLISM) GENE ANALYSIS, COMMON AND SELECT RARE VARIANTS (IE, *2, *3, *4, *4N, *5, *6, *7, *8, *9, *10, *11, *12, *13, *14A, *14B, *15, *17, *29, *35, *36, *41, *57, *61, *63, *68, *83, *XN)

Group 2 Paragraph:

Tier 1 Individual Review Codes

Coverage may be provided for the genetic tests submitted under the following Tier 1 CPT codes, if documentation supports medical necessity:

Please refer to the Indications and Limitations of Coverage section (L35000) and the ICD-10-CM diagnosis to CPT procedure groupings below. Not all procedure codes have related diagnosis codes listed.

Group 2 Codes: (51 Codes)

CODE	DESCRIPTION
81177	ATN1 (ATROPHIN 1) (EG, DENTATORUBRAL-PALLIDOLUYSIAN ATROPHY) GENE ANALYSIS, EVALUATION TO DETECT ABNORMAL (EG, EXPANDED) ALLELES
81178	ATXN1 (ATAXIN 1) (EG, SPINOCEREBELLAR ATAXIA) GENE ANALYSIS, EVALUATION TO DETECT ABNORMAL (EG, EXPANDED) ALLELES
81179	ATXN2 (ATAXIN 2) (EG, SPINOCEREBELLAR ATAXIA) GENE ANALYSIS, EVALUATION TO DETECT ABNORMAL (EG, EXPANDED) ALLELES
81180	ATXN3 (ATAXIN 3) (EG, SPINOCEREBELLAR ATAXIA, MACHADO-JOSEPH DISEASE) GENE ANALYSIS, EVALUATION TO DETECT ABNORMAL (EG, EXPANDED) ALLELES
81181	ATXN7 (ATAXIN 7) (EG, SPINOCEREBELLAR ATAXIA) GENE ANALYSIS, EVALUATION TO DETECT ABNORMAL (EG, EXPANDED) ALLELES
81182	ATXN8OS (ATXN8 OPPOSITE STRAND [NON-PROTEIN CODING]) (EG, SPINOCEREBELLAR ATAXIA) GENE ANALYSIS, EVALUATION TO DETECT ABNORMAL (EG, EXPANDED) ALLELES

CODE	DESCRIPTION
81183	ATXN10 (ATAXIN 10) (EG, SPINOCEREBELLAR ATAXIA) GENE ANALYSIS, EVALUATION TO DETECT ABNORMAL (EG, EXPANDED) ALLELES
81184	CACNA1A (CALCIUM VOLTAGE-GATED CHANNEL SUBUNIT ALPHA1 A) (EG, SPINOCEREBELLAR ATAXIA) GENE ANALYSIS; EVALUATION TO DETECT ABNORMAL (EG, EXPANDED) ALLELES
81185	CACNA1A (CALCIUM VOLTAGE-GATED CHANNEL SUBUNIT ALPHA1 A) (EG, SPINOCEREBELLAR ATAXIA) GENE ANALYSIS; FULL GENE SEQUENCE
81186	CACNA1A (CALCIUM VOLTAGE-GATED CHANNEL SUBUNIT ALPHA1 A) (EG, SPINOCEREBELLAR ATAXIA) GENE ANALYSIS; KNOWN FAMILIAL VARIANT
81187	CNBP (CCHC-TYPE ZINC FINGER NUCLEIC ACID BINDING PROTEIN) (EG, MYOTONIC DYSTROPHY TYPE 2) GENE ANALYSIS, EVALUATION TO DETECT ABNORMAL (EG, EXPANDED) ALLELES
81188	CSTB (CYSTATIN B) (EG, UNVERRICHT-LUNDBORG DISEASE) GENE ANALYSIS; EVALUATION TO DETECT ABNORMAL (EG, EXPANDED) ALLELES
81189	CSTB (CYSTATIN B) (EG, UNVERRICHT-LUNDBORG DISEASE) GENE ANALYSIS; FULL GENE SEQUENCE
81190	CSTB (CYSTATIN B) (EG, UNVERRICHT-LUNDBORG DISEASE) GENE ANALYSIS; KNOWN FAMILIAL VARIANT(S)
81191	NTRK1 (NEUROTROPHIC RECEPTOR TYROSINE KINASE 1) (EG, SOLID TUMORS) TRANSLOCATION ANALYSIS
81192	NTRK2 (NEUROTROPHIC RECEPTOR TYROSINE KINASE 2) (EG, SOLID TUMORS) TRANSLOCATION ANALYSIS
81193	NTRK3 (NEUROTROPHIC RECEPTOR TYROSINE KINASE 3) (EG, SOLID TUMORS) TRANSLOCATION ANALYSIS
81194	NTRK (NEUROTROPHIC RECEPTOR TYROSINE KINASE 1, 2, AND 3) (EG, SOLID TUMORS) TRANSLOCATION ANALYSIS
81233	BTK (BRUTON'S TYROSINE KINASE) (EG, CHRONIC LYMPHOCYTIC LEUKEMIA) GENE ANALYSIS, COMMON VARIANTS (EG, C481S, C481R, C481F)
81277	CYTOGENOMIC NEOPLASIA (GENOME-WIDE) MICROARRAY ANALYSIS, INTERROGATION OF GENOMIC REGIONS FOR COPY NUMBER AND LOSS-OF-HETEROZYGOSITY VARIANTS FOR CHROMOSOMAL ABNORMALITIES
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,

CODE	DESCRIPTION
	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
81306	NUDT15 (NUDIX HYDROLASE 15) (EG, DRUG METABOLISM) GENE ANALYSIS, COMMON VARIANT(S) (EG, *2, *3, *4, *5, *6)
81312	PABPN1 (POLY[A] BINDING PROTEIN NUCLEAR 1) (EG, OCULOPHARYNGEAL MUSCULAR DYSTROPHY) GENE ANALYSIS, EVALUATION TO DETECT ABNORMAL (EG, EXPANDED) ALLELES
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
81320	PLCG2 (PHOSPHOLIPASE C GAMMA 2) (EG, CHRONIC LYMPHOCYTIC LEUKEMIA) GENE ANALYSIS, COMMON VARIANTS (EG, R665W, S707F, L845F)

CODE	DESCRIPTION
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
81333	TGFBI (TRANSFORMING GROWTH FACTOR BETA-INDUCED) (EG, CORNEAL DYSTROPHY) GENE ANALYSIS, COMMON VARIANTS (EG, R124H, R124C, R124L, R555W, R555Q)
81343	PPP2R2B (PROTEIN PHOSPHATASE 2 REGULATORY SUBUNIT BBETA) (EG, SPINOCEREBELLAR ATAXIA) GENE ANALYSIS, EVALUATION TO DETECT ABNORMAL (EG, EXPANDED) ALLELES
81344	TBP (TATA BOX BINDING PROTEIN) (EG, SPINOCEREBELLAR ATAXIA) GENE ANALYSIS, EVALUATION TO DETECT ABNORMAL (EG, EXPANDED) ALLELES
81352	TP53 (TUMOR PROTEIN 53) (EG, LI-FRAUMENI SYNDROME) GENE ANALYSIS; TARGETED SEQUENCE ANALYSIS (EG, 4 ONCOLOGY)
81353	TP53 (TUMOR PROTEIN 53) (EG, LI-FRAUMENI SYNDROME) GENE ANALYSIS; KNOWN FAMILIAL VARIANT
81357	U2AF1 (U2 SMALL NUCLEAR RNA AUXILIARY FACTOR 1) (EG, MYELODYSPLASTIC SYNDROME, ACUTE MYELOID LEUKEMIA) GENE ANALYSIS, COMMON VARIANTS (EG, S34F, S34Y, Q157R, Q157P)
81360	ZRSR2 (ZINC FINGER CCCH-TYPE, RNA BINDING MOTIF AND SERINE/ARGININE-RICH 2) (EG, MYELODYSPLASTIC SYNDROME, ACUTE MYELOID LEUKEMIA) GENE ANALYSIS, COMMON VARIANT(S) (EG, E65FS, E122FS, R448FS)
81419	EPILEPSY GENOMIC SEQUENCE ANALYSIS PANEL, MUST INCLUDE ANALYSES FOR ALDH7A1, CACNA1A, CDKL5, CHD2, GABRG2, GRIN2A, KCNQ2, MECP2, PCDH19, POLG, PRRT2, SCN1A, SCN1B, SCN2A, SCN8A, SLC2A1, SLC9A6, STXBP1, SYNGAP1, TCF4, TPP1, TSC1, TSC2, AND ZEB2
81529	ONCOLOGY (CUTANEOUS MELANOMA), MRNA, GENE EXPRESSION PROFILING BY REAL-TIME RT-PCR OF 31 GENES (28 CONTENT AND 3 HOUSEKEEPING), UTILIZING FORMALIN-FIXED PARAFFIN-EMBEDDED TISSUE, ALGORITHM REPORTED AS RECURRENCE RISK, INCLUDING LIKELIHOOD OF SENTINEL LYMPH NODE METASTASIS
81542	ONCOLOGY (PROSTATE), MRNA, MICROARRAY GENE EXPRESSION PROFILING OF 22 CONTENT GENES, UTILIZING FORMALIN-FIXED PARAFFIN-EMBEDDED TISSUE, ALGORITHM REPORTED AS METASTASIS RISK SCORE
81554	PULMONARY DISEASE (IDIOPATHIC PULMONARY FIBROSIS [IPF]), MRNA, GENE EXPRESSION ANALYSIS OF 190 GENES, UTILIZING TRANSBRONCHIAL BIOPSIES,

CODE	DESCRIPTION
	DIAGNOSTIC ALGORITHM REPORTED AS CATEGORICAL RESULT (EG, POSITIVE OR NEGATIVE FOR HIGH PROBABILITY OF USUAL INTERSTITIAL PNEUMONIA [UIP])
81599	UNLISTED MULTIANALYTE ASSAY WITH ALGORITHMIC ANALYSIS

Group 3 Paragraph:

Tier 1 Non-covered Codes

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: (120 Codes)

CODE	DESCRIPTION
81105 - 81112	HUMAN PLATELET ANTIGEN 1 GENOTYPING (HPA-1), ITGB3 (INTEGRIN, BETA 3 [PLATELET GLYCOPROTEIN IIIA], ANTIGEN CD61 [GPIIIA]) (EG, NEONATAL ALLOIMMUNE THROMBOCYTOPENIA [NAIT], POST-TRANSFUSION PURPURA), GENE ANALYSIS, COMMON VARIANT, HPA-1A/B (L33P) - HUMAN PLATELET ANTIGEN 15 GENOTYPING (HPA-15), CD109 (CD109 MOLECULE) (EG, NEONATAL ALLOIMMUNE THROMBOCYTOPENIA [NAIT], POST-TRANSFUSION PURPURA), GENE ANALYSIS, COMMON VARIANT, HPA-15A/B (S682Y)
81161	DMD (DYSTROPHIN) (EG, DUCHENNE/BECKER MUSCULAR DYSTROPHY) DELETION ANALYSIS, AND DUPLICATION ANALYSIS, IF PERFORMED
81171	AFF2 (AF4/FMR2 FAMILY, MEMBER 2 [FMR2]) (EG, FRAGILE X MENTAL RETARDATION 2 [FRAXE]) GENE ANALYSIS; EVALUATION TO DETECT ABNORMAL (EG, EXPANDED) ALLELES
81172	AFF2 (AF4/FMR2 FAMILY, MEMBER 2 [FMR2]) (EG, FRAGILE X MENTAL RETARDATION 2 [FRAXE]) GENE ANALYSIS; CHARACTERIZATION OF ALLELES (EG, EXPANDED SIZE AND METHYLATION STATUS)
81173	AR (ANDROGEN RECEPTOR) (EG, SPINAL AND BULBAR MUSCULAR ATROPHY, KENNEDY DISEASE, X CHROMOSOME INACTIVATION) GENE ANALYSIS; FULL GENE SEQUENCE
81174	AR (ANDROGEN RECEPTOR) (EG, SPINAL AND BULBAR MUSCULAR ATROPHY, KENNEDY DISEASE, X CHROMOSOME INACTIVATION) GENE ANALYSIS; KNOWN FAMILIAL VARIANT
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

CODE	DESCRIPTION
81203	APC (ADENOMATOUS POLYPOSIS COLI) (EG, FAMILIAL ADENOMATOSIS POLYPOSIS [FAP], ATTENUATED FAP) GENE ANALYSIS; DUPLICATION/DELETION VARIANTS
81204	AR (ANDROGEN RECEPTOR) (EG, SPINAL AND BULBAR MUSCULAR ATROPHY, KENNEDY DISEASE, X CHROMOSOME INACTIVATION) GENE ANALYSIS; CHARACTERIZATION OF ALLELES (EG, EXPANDED SIZE OR METHYLATION STATUS)
81205	BCKDHB (BRANCHED-CHAIN KETO ACID DEHYDROGENASE E1, BETA POLYPEPTIDE) (EG, MAPLE SYRUP URINE DISEASE) GENE ANALYSIS, COMMON VARIANTS (EG, R183P, G278S, E422X)
81228	CYTOGENOMIC (GENOME-WIDE) ANALYSIS FOR CONSTITUTIONAL CHROMOSOMAL ABNORMALITIES; INTERROGATION OF GENOMIC REGIONS FOR COPY NUMBER VARIANTS, COMPARATIVE GENOMIC HYBRIDIZATION [CGH] MICROARRAY ANALYSIS
81229	CYTOGENOMIC (GENOME-WIDE) ANALYSIS FOR CONSTITUTIONAL CHROMOSOMAL ABNORMALITIES; INTERROGATION OF GENOMIC REGIONS FOR COPY NUMBER AND SINGLE NUCLEOTIDE POLYMORPHISM (SNP) VARIANTS, COMPARATIVE GENOMIC HYBRIDIZATION (CGH) MICROARRAY ANALYSIS
81230	CYP3A4 (CYTOCHROME P450 FAMILY 3 SUBFAMILY A MEMBER 4) (EG, DRUG METABOLISM), GENE ANALYSIS, COMMON VARIANT(S) (EG, *2, *22)
81231	CYP3A5 (CYTOCHROME P450 FAMILY 3 SUBFAMILY A MEMBER 5) (EG, DRUG METABOLISM), GENE ANALYSIS, COMMON VARIANTS (EG, *2, *3, *4, *5, *6, *7)
81232	DPYD (DIHYDROPYRIMIDINE DEHYDROGENASE) (EG, 5-FLUOROURACIL/5-FU AND CAPECITABINE DRUG METABOLISM), GENE ANALYSIS, COMMON VARIANT(S) (EG, *2A, *4, *5, *6)
81234	DMPK (DM1 PROTEIN KINASE) (EG, MYOTONIC DYSTROPHY TYPE 1) GENE ANALYSIS; EVALUATION TO DETECT ABNORMAL (EXPANDED) ALLELES
81238	F9 (COAGULATION FACTOR IX) (EG, HEMOPHILIA B), FULL GENE SEQUENCE
81239	DMPK (DM1 PROTEIN KINASE) (EG, MYOTONIC DYSTROPHY TYPE 1) GENE ANALYSIS; CHARACTERIZATION OF ALLELES (EG, EXPANDED SIZE)
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

CODE	DESCRIPTION
	RETARDATION) GENE ANALYSIS; CHARACTERIZATION OF ALLELES (EG, EXPANDED SIZE AND PROMOTER METHYLATION STATUS)
81247	G6PD (GLUCOSE-6-PHOSPHATE DEHYDROGENASE) (EG, HEMOLYTIC ANEMIA, JAUNDICE), GENE ANALYSIS; COMMON VARIANT(S) (EG, A, A-)
81248	G6PD (GLUCOSE-6-PHOSPHATE DEHYDROGENASE) (EG, HEMOLYTIC ANEMIA, JAUNDICE), GENE ANALYSIS; KNOWN FAMILIAL VARIANT(S)
81249	G6PD (GLUCOSE-6-PHOSPHATE DEHYDROGENASE) (EG, HEMOLYTIC ANEMIA, JAUNDICE), GENE ANALYSIS; FULL GENE SEQUENCE
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; COMMON DELETIONS OR VARIANT (EG, SOUTHEAST ASIAN, THAI, FILIPINO, MEDITERRANEAN, ALPHA3.7, ALPHA4.2, ALPHA20.5, CONSTANT SPRING)
81258	HBA1/HBA2 (ALPHA GLOBIN 1 AND ALPHA GLOBIN 2) (EG, ALPHA THALASSEMIA, HB BART HYDROPS FETALIS SYNDROME, HBH DISEASE), GENE ANALYSIS; KNOWN FAMILIAL VARIANT
81259	HBA1/HBA2 (ALPHA GLOBIN 1 AND ALPHA GLOBIN 2) (EG, ALPHA THALASSEMIA, HB BART HYDROPS FETALIS SYNDROME, HBH DISEASE), GENE ANALYSIS; FULL GENE SEQUENCE
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)
81269	HBA1/HBA2 (ALPHA GLOBIN 1 AND ALPHA GLOBIN 2) (EG, ALPHA THALASSEMIA, HB BART HYDROPS FETALIS SYNDROME, HBH DISEASE), GENE ANALYSIS; DUPLICATION/DELETION VARIANTS

CODE	DESCRIPTION
81271	HTT (HUNTINGTIN) (EG, HUNTINGTON DISEASE) GENE ANALYSIS; EVALUATION TO DETECT ABNORMAL (EG, EXPANDED) ALLELES
81274	HTT (HUNTINGTIN) (EG, HUNTINGTON DISEASE) GENE ANALYSIS; CHARACTERIZATION OF ALLELES (EG, EXPANDED SIZE)
81283	IFNL3 (INTERFERON, LAMBDA 3) (EG, DRUG RESPONSE), GENE ANALYSIS, RS12979860 VARIANT
81284	FXN (FRATAXIN) (EG, FRIEDREICH ATAXIA) GENE ANALYSIS; EVALUATION TO DETECT ABNORMAL (EXPANDED) ALLELES
81285	FXN (FRATAXIN) (EG, FRIEDREICH ATAXIA) GENE ANALYSIS; CHARACTERIZATION OF ALLELES (EG, EXPANDED SIZE)
81286	FXN (FRATAXIN) (EG, FRIEDREICH ATAXIA) GENE ANALYSIS; FULL GENE SEQUENCE
81289	FXN (FRATAXIN) (EG, FRIEDREICH ATAXIA) GENE ANALYSIS; KNOWN FAMILIAL VARIANT(S)
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
81327	SEPT9 (SEPTIN9) (EG, COLORECTAL CANCER) PROMOTER METHYLATION ANALYSIS
81328	SLCO1B1 (SOLUTE CARRIER ORGANIC ANION TRANSPORTER FAMILY, MEMBER 1B1) (EG, ADVERSE DRUG REACTION), GENE ANALYSIS, COMMON VARIANT(S) (EG, *5)
81329	SMN1 (SURVIVAL OF MOTOR NEURON 1, TELOMERIC) (EG, SPINAL MUSCULAR

CODE	DESCRIPTION
	ATROPHY) GENE ANALYSIS; DOSAGE/DELETION ANALYSIS (EG, CARRIER TESTING), INCLUDES SMN2 (SURVIVAL OF MOTOR NEURON 2, CENTROMERIC) ANALYSIS, IF PERFORMED
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
81336	SMN1 (SURVIVAL OF MOTOR NEURON 1, TELOMERIC) (EG, SPINAL MUSCULAR ATROPHY) GENE ANALYSIS; FULL GENE SEQUENCE
81337	SMN1 (SURVIVAL OF MOTOR NEURON 1, TELOMERIC) (EG, SPINAL MUSCULAR ATROPHY) GENE ANALYSIS; KNOWN FAMILIAL SEQUENCE VARIANT(S)
81346	TYMS (THYMIDYLATE SYNTHETASE) (EG, 5-FLUOROURACIL/5-FU DRUG METABOLISM), GENE ANALYSIS, COMMON VARIANT(S) (EG, TANDEM REPEAT VARIANT)
81349	CYTOGENOMIC (GENOME-WIDE) ANALYSIS FOR CONSTITUTIONAL CHROMOSOMAL ABNORMALITIES; INTERROGATION OF GENOMIC REGIONS FOR COPY NUMBER AND LOSS-OF-HETEROZYGOSITY VARIANTS, LOW-PASS SEQUENCING ANALYSIS
81350	UGT1A1 (UDP GLUCURONOSYLTRANSFERASE 1 FAMILY, POLYPEPTIDE A1) (EG, DRUG METABOLISM, HEREDITARY UNCONJUGATED HYPERBILIRUBINEMIA [GILBERT SYNDROME]) GENE ANALYSIS, COMMON VARIANTS (EG, *28, *36, *37)
81355	VKORC1 (VITAMIN K EPOXIDE REDUCTASE COMPLEX, SUBUNIT 1) (EG, WARFARIN METABOLISM), GENE ANALYSIS, COMMON VARIANT(S) (EG, -1639G>A, C.173+1000C>T)
81361 - 81364	HBB (HEMOGLOBIN, SUBUNIT BETA) (EG, SICKLE CELL ANEMIA, BETA THALASSEMIA, HEMOGLOBINOPATHY); COMMON VARIANT(S) (EG, HBS, HBC, HBE) - HBB (HEMOGLOBIN, SUBUNIT BETA) (EG, SICKLE CELL ANEMIA, BETA THALASSEMIA, HEMOGLOBINOPATHY); FULL GENE SEQUENCE
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

CODE	DESCRIPTION
	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	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,

CODE	DESCRIPTION
	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 10 GENES, ALWAYS INCLUDING BRCA1, BRCA2, CDH1, MLH1, MSH2, MSH6, PALB2, PTEN, 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	HEREDITARY CARDIOMYOPATHY (EG, HYPERTROPHIC CARDIOMYOPATHY, DILATED CARDIOMYOPATHY, ARRHYTHMOGENIC RIGHT VENTRICULAR CARDIOMYOPATHY), GENOMIC SEQUENCE ANALYSIS PANEL, MUST INCLUDE SEQUENCING OF AT LEAST 5 CARDIOMYOPATHY-RELATED GENES (EG, DSG2, MYBPC3, MYH7, PKP2, TTN)
81440	NUCLEAR ENCODED MITOCHONDRIAL GENES (EG, NEUROLOGIC OR MYOPATHIC PHENOTYPES), GENOMIC SEQUENCE PANEL, MUST INCLUDE ANALYSIS OF AT

CODE	DESCRIPTION
	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
81443	GENETIC TESTING FOR SEVERE INHERITED CONDITIONS (EG, CYSTIC FIBROSIS, ASHKENAZI JEWISH-ASSOCIATED DISORDERS [EG, BLOOM SYNDROME, CANAVAN DISEASE, FANCONI ANEMIA TYPE C, MUCOLIPIDOSIS TYPE VI, GAUCHER DISEASE, TAY-SACHS DISEASE], BETA HEMOGLOBINOPATHIES, PHENYLKETONURIA, GALACTOSEMIA), GENOMIC SEQUENCE ANALYSIS PANEL, MUST INCLUDE SEQUENCING OF AT LEAST 15 GENES (EG, ACADM, ARSA, ASPA, ATP7B, BCKDHA, BCKDHB, BLM, CFTR, DHCR7, FANCC, G6PC, GAA, GALT, GBA, GBE1, HBB, HEXA, IKBKAP, MCOLN1, PAH)
81448	HEREDITARY PERIPHERAL NEUROPATHIES (EG, CHARCOT-MARIE-TOOTH, SPASTIC PARAPLEGIA), GENOMIC SEQUENCE ANALYSIS PANEL, MUST INCLUDE SEQUENCING OF AT LEAST 5 PERIPHERAL NEUROPATHY-RELATED GENES (EG, BSCL2, GJB1, MFN2, MPZ, REEP1, SPAST, SPG11, SPTLC1)
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

CODE	DESCRIPTION
	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
CODE	DESCRIPTION
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
81521	ONCOLOGY (BREAST), MRNA, MICROARRAY GENE EXPRESSION PROFILING OF 70 CONTENT GENES AND 465 HOUSEKEEPING GENES, UTILIZING FRESH FROZEN OR FORMALIN-FIXED PARAFFIN-EMBEDDED TISSUE, ALGORITHM REPORTED AS INDEX RELATED TO RISK OF DISTANT METASTASIS
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
81541	ONCOLOGY (PROSTATE), MRNA GENE EXPRESSION PROFILING BY REAL-TIME RT-PCR OF 46 GENES (31 CONTENT AND 15 HOUSEKEEPING), UTILIZING FORMALIN-

CODE	DESCRIPTION
	FIXED PARAFFIN-EMBEDDED TISSUE, ALGORITHM REPORTED AS A DISEASE-SPECIFIC MORTALITY RISK SCORE
81551	ONCOLOGY (PROSTATE), PROMOTER METHYLATION PROFILING BY REAL-TIME PCR OF 3 GENES (GSTP1, APC, RASSF1), UTILIZING FORMALIN-FIXED PARAFFIN-EMBEDDED TISSUE, ALGORITHM REPORTED AS A LIKELIHOOD OF PROSTATE CANCER DETECTION ON REPEAT BIOPSY

Group 4 Paragraph:

Tier 2 CPT and NOC Codes

Refer to indications and Limitations of Coverage section (L35000).

Tier 2/NOC Covered Code/Gene Combinations

Limited coverage may be provided for specific genes reported below:

81400 ACE, F13B, F5, F7, FGB

81401 CBFB-MYH11, E2A/PBX1, EML4-ALK, ETV6-RUNX1, EWSR1/ERG, EWSR1/FLI1, EWSR1/WT1, F11coagulation factor XI, FIP1L1-PDGFR, FOXO1/PAX3, FOXO1/PAX7, MUTYH (mutY homolog [E.coli]), NPM/ALK, PAX8/PPARG, RUNX1/RUNX1T1

81403 F8 (coagulation factor VIII), VHL (von Hippel-Lindau tumor suppressor)

81404 CDKN2A (cyclin-dependent kinase inhibitor 2A), PRSS1 (protease, serine, 1 [trypsin 1]), MEN1 (multiple endocrine neoplasia 1) (eg, multiple endocrine neoplasia type 1, Wermer syndrome), duplication/deletion, TP53 (tumor protein 53) (e.g. tumor samples), targeted sequence analysis of 2-5 exons, VHL (von Hippel-Lindau tumor suppressor)

81405 TP53 (tumor protein 53) (e.g. Li-Fraumeni syndrome, tumor samples), full gene sequence or targeted sequence analysis of >5 exons,

81406 ATP7B (ATPase, Cu++ transporting, beta polypeptide)

Tier 2/NOC Individual Review Code/Gene Combinations

Any genetic test reported with a Tier 2 CPT code, not listed above or below, is subject to individual review.

Tier 2/NOC Non-covered Code/Gene Combinations

The following individual Tier 2 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 article):

81400 ABCC8, ACADM, AGTR1, CCR5, CLRN1, DYT1 (TOR1A), FGFR3, IL28B, IVD, TOR1A

81401 ADRB2, APOE, ATN1, CFH/ARMS2, DEK/NUP214, FGFR3, GALT (galactose-1-phosphate uridylyltransferase), H19, KCNQ10T1 (KCNQ1 overlapping transcript 1), MEG3/DLK1, MLL/AFF, MT-ATP6, MT-ND4, MT-ND6, MT-ND5 mitochondrially encoded tRNA leucine 1 [UUA/G] mitochondrially encoded NADH dehydrogenase 5), MT-RNR1 (mitochondrially encoded 12S RNA), MT-TK (mitochondrially encoded tRNA lysine), MT-TL1, MT-TS1, PRSS1 (protease, serine, 1 [trypsin 1])

81402 CYP21A2, Chromosome 18q-, MEFV (Mediterranean fever) (eg, familial Mediterranean fever), TRD 81402 Uniparental disomy (UPD)

81403 ANG (angiogenin, ribonuclease, RNase A family, 5), FGFR3 (fibroblast growth factor receptor 3) one exon, GJB1 (gap junction protein, beta 1) (eg, Charcot-Marie-Tooth X-linked), full gene sequence, HRAS (v-Ha-ras Harvey rat sarcoma viral oncogene homolog Costello syndrome), MT-RNR1 (mitochondrially encoded 12S RNA), MT-TS1 (mitochondrially encoded tRNA serine 1)

81404 ACADS (acyl-CoA dehydrogenase), AQP2 (aquaporin 2 [collecting duct]), ARX (aristaless related homeobox), BTD (biotinidase), CAV3 (caveolin 3) (eg, CAV3-related distal myopathy, limb-girdle muscular dystrophy type 1C), full gene sequence, CLRN1 (clarin 1), CYP1B1 (cytochrome P450, family 1, subfamily B, polypeptide 1), EGR2 (early growth response 2) (eg, Charcot-Marie-Tooth), FGFR2 (fibroblast growth factor receptor 2) (2 EXONS), FGFR3 (fibroblast growth factor receptor 3) (4 EXONS), FKRP (Fukutin related protein), FOXG1 (forkhead box G1), FSHMD1A (facioscapulohumeral muscular dystrophy 1A), FSHMD1A (facioscapulohumeral muscular dystrophy 1A), HNF1B (HNF1 homeobox B), HRAS (v-Ha-ras Harvey rat sarcoma viral oncogene homolog), KCNJ10 (potassium inwardly-rectifying channel, subfamily J, member 10), SLC25A4 (solute carrier family 25 [mitochondrial carrier; adenine nucleotide translocation], VWF (von Willebrand factor)

81405 CASR (CAR, EIG8, extracellular calcium-sensing receptor, FHH, FIH, GPRC2A, HHC, HHC1, NSHPT, PCAR1), CYP21A2 (cytochrome P450, family 21, subfamily A, polypeptide2), MPZ (myelin protein zero)

81406 ACADVL (acyl-CoA dehydrogenase, very long chain), CBS (cystathionine-beta-synthase), CDKL5 (cyclin-dependent kinase-like 5) DLAT (dihydrolipoamide S-acetyltransferase), DLD (dihydrolipoamide dehydrogenase), F8 (coagulation factor VIII), GALT (galactose-1-phosphate uridylyltransferase), HADHA (hydroxyacyl-CoA dehydrogenase/3-ketoacyl-CoA thiolase/enoyl-CoA hydratase [trifunctional protein] alpha subunit), HEXA (hexosaminidase A, alpha polypeptide), LMNA (lamin A/C), MUTYH (mutY homolog [E. coli]), NF2 (neurofibromin 2 [merlin]), NSD1 (nuclear receptor binding SET domain protein 1), PAH (phenylalanine hydroxylase), PAX2 (paired box 2), PDHA1 (pyruvate dehydrogenase [lipoamide] alpha1), POLG (polymerase [DNA directed], gamma), PRKAG2 (protein kinase, AMP-activated, gamma 2 non-catalytic subunit), PTPN11 (protein tyrosine phosphatase, non-receptor type 11), RET (ret-proto-oncogene) (eg, Hirschsprung disease), full gene sequence, SLC9A6 (solute carrier family 9 [sodium/hydrogen exchanger] member 6), SOS1 (son of sevenless homolog 1), TAZ (tafazzin), TSC1 (tuberous sclerosis 1), TSC2 (tuberous sclerosis 2), UBE3A (ubiquitin protein ligase)

81407 Level 8 Molecular Pathology Procedures, F8 (coagulation factor VIII)

81408 Level 9 Molecular Pathology Procedures

81479 PIK3C, PI3Ks, PI(3)Ks, PI-3Ks, AKT1, MEK1, VEGFR2 (CD309, FLK1, VEGFR), LPA intron 25 genotype, KIF6, SPG4, C9orf72, MLH1, AIRE (APSI), SDA2, HAX1 (HAX1_HUMAN, HCLS1- associated protein X-1, HCLSBP1, HS1-associating protein X-1, HS1 binding protein, HS1-binding protein 1, HS1BP1, HSP1BP-1)

Note: When a panel with greater than one or less than five genes is ordered, use the corresponding existing panel CPT code or CPT code 81479 if none exists.

Group 4 Codes: (10 Codes)

CODE	DESCRIPTION
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) UGT1A1 (UDP GLUCURONOSYLTRANSFERASE 1 FAMILY, POLYPEPTIDE A1) (EG, HEREDITARY UNCONJUGATED HYPERBILIRUBINEMIA [CRIGLER-NAJJAR SYNDROME]) FULL GENE SEQUENCE
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, REGIONALLY TARGETED CYTOGENOMIC ARRAY ANALYSIS)
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)

CODE	DESCRIPTION
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) APOB (APOLIPOPROTEIN B) (EG, FAMILIAL HYPERCHOLESTEROLEMIA TYPE B) FULL GENE SEQUENCE
81408	MOLECULAR PATHOLOGY PROCEDURE, LEVEL 9 (EG, ANALYSIS OF >50 EXONS IN A SINGLE GENE BY DNA SEQUENCE ANALYSIS)
81479	UNLISTED MOLECULAR PATHOLOGY PROCEDURE

CPT/HCPCS Modifiers

N/A

ICD-10-CM Codes that Support Medical Necessity

Group 1 Paragraph:

CPT codes 81162-81167, 81212, 81215, 81216, 81217 are considered medically necessary for the following ICD-10-CM codes:

Group 1 Codes: (78 Codes)

CODE	DESCRIPTION
C25.0	Malignant neoplasm of head of pancreas
C25.1	Malignant neoplasm of body of pancreas
C25.2	Malignant neoplasm of tail of pancreas
C25.3	Malignant neoplasm of pancreatic duct
C25.4	Malignant neoplasm of endocrine pancreas
C25.7	Malignant neoplasm of other parts of pancreas
C25.8	Malignant neoplasm of overlapping sites of pancreas
C25.9	Malignant neoplasm of pancreas, unspecified
C48.1	Malignant neoplasm of specified parts of peritoneum
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

CODE	DESCRIPTION
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

CODE	DESCRIPTION
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
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
C56.1	Malignant neoplasm of right ovary
C56.2	Malignant neoplasm of left ovary
C56.3	Malignant neoplasm of bilateral ovaries
C56.9	Malignant neoplasm of unspecified ovary
C57.00	Malignant neoplasm of unspecified fallopian tube
C57.01	Malignant neoplasm of right fallopian tube
C57.02	Malignant neoplasm of left fallopian tube
C61	Malignant neoplasm of prostate
D05.11	Intraductal carcinoma in situ of right breast
D05.12	Intraductal carcinoma in situ of left breast
Z85.07	Personal history of malignant neoplasm of pancreas
Z85.3	Personal history of malignant neoplasm of breast
Z85.43	Personal history of malignant neoplasm of ovary
Z85.46	Personal history of malignant neoplasm of prostate
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: (9 Codes)

CODE	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

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: (14 Codes)

CODE	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
D47.3	Essential (hemorrhagic) thrombocythemia
D72.829	Elevated white blood cell count, unspecified

Group 4 Paragraph:

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

Group 4 Codes: (93 Codes)

CODE	DESCRIPTION
C17.0 - C17.9	Malignant neoplasm of duodenum - Malignant neoplasm of small intestine, unspecified

CODE	DESCRIPTION
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
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: (28 Codes)

CODE	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

CODE	DESCRIPTION
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
C92.90	Myeloid leukemia, unspecified, not having achieved remission
C92.92	Myeloid leukemia, unspecified in relapse
C93.00	Acute monoblastic/monocytic leukemia, not having achieved remission
C93.02	Acute monoblastic/monocytic leukemia, in relapse
C94.00	Acute erythroid leukemia, not having achieved remission
C94.02	Acute erythroid leukemia, in relapse
C94.80	Other specified leukemias not having achieved remission
C94.82	Other specified leukemias, in relapse
C95.00	Acute leukemia of unspecified cell type not having achieved remission
C95.02	Acute leukemia of unspecified cell type, in relapse
C95.90	Leukemia, unspecified not having achieved remission
C95.92	Leukemia, unspecified, in relapse
R16.1	Splenomegaly, not elsewhere classified
R16.2	Hepatomegaly with splenomegaly, not elsewhere classified

Group 6 Paragraph:

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

Group 6 Codes: (1 Code)

CODE	DESCRIPTION
R97.20	Elevated prostate specific antigen [PSA]

Group 7 Paragraph:

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

Group 7 Codes: (3 Codes)

CODE	DESCRIPTION
C92.40 - C92.42	Acute promyelocytic leukemia, not having achieved remission - Acute promyelocytic

CODE	DESCRIPTION
	leukemia, in relapse

Group 8 Paragraph:

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

Group 8 Codes: (42 Codes)

CODE	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

CODE	DESCRIPTION
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
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 9 Paragraph:

CPT code 81226 (CYP2d6) is considered medically necessary for the following ICD-10-CM codes:
PLA code 0070U is effective for services, rendered on or after May 15, 2021.

Group 9 Codes: (2 Codes)

CODE	DESCRIPTION
E75.22	Gaucher disease

CODE	DESCRIPTION
G10	Huntington's disease

Group 10 Paragraph:

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

Group 10 Codes: (17 Codes)

CODE	DESCRIPTION
C33 - C34.92	Malignant neoplasm of trachea - Malignant neoplasm of unspecified part of left bronchus or lung

Group 11 Paragraph:

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

Group 11 Codes: (28 Codes)

CODE	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
C92.90	Myeloid leukemia, unspecified, not having achieved remission
C92.92	Myeloid leukemia, unspecified in relapse

CODE	DESCRIPTION
C93.00	Acute monoblastic/monocytic leukemia, not having achieved remission
C93.02	Acute monoblastic/monocytic leukemia, in relapse
C94.00	Acute erythroid leukemia, not having achieved remission
C94.02	Acute erythroid leukemia, in relapse
C94.80	Other specified leukemias not having achieved remission
C94.82	Other specified leukemias, in relapse
C95.00	Acute leukemia of unspecified cell type not having achieved remission
C95.02	Acute leukemia of unspecified cell type, in relapse
C95.90	Leukemia, unspecified not having achieved remission
C95.92	Leukemia, unspecified, in relapse
R16.1	Splenomegaly, not elsewhere classified
R16.2	Hepatomegaly with splenomegaly, not elsewhere classified

Group 12 Paragraph:

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

Group 12 Codes: (5 Codes)

CODE	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 13 Paragraph:

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

Group 13 Codes: (205 Codes)

CODE	DESCRIPTION
C82.00 - C83.99	Follicular lymphoma grade I, unspecified site - Non-follicular (diffuse) lymphoma, unspecified, extranodal and solid organ sites
C85.10 - C85.99	Unspecified B-cell lymphoma, unspecified site - Non-Hodgkin lymphoma, unspecified, extranodal and solid organ sites

CODE	DESCRIPTION
C91.00 - C91.02	Acute lymphoblastic leukemia not having achieved remission - Acute lymphoblastic leukemia, in relapse
D72.828	Other elevated white blood cell count
D72.89	Other specified disorders of white blood cells

Group 14 Paragraph:

CPT codes 81270 (JAK2), 81338 (MPL), 81339 (MPL), 81279 (JAK2 exons 12 and 13), 81219 (CALR), and 0027U (JAK2 exons 12-15) are considered medically necessary for the following ICD-10-CM codes when criteria in Indications and Limitations of Coverage are met:

Group 14 Codes: (34 Codes)

CODE	DESCRIPTION
C88.8	Other malignant immunoproliferative diseases
C92.20	Atypical chronic myeloid leukemia, BCR/ABL-negative, not having achieved remission
C92.22	Atypical chronic myeloid leukemia, BCR/ABL-negative, in relapse
C93.10	Chronic myelomonocytic leukemia not having achieved remission
C93.12	Chronic myelomonocytic leukemia, in relapse
C93.Z0	Other monocytic leukemia, not having achieved remission
C93.Z2	Other monocytic leukemia, in relapse
C93.90	Monocytic leukemia, unspecified, not having achieved remission
C93.92	Monocytic leukemia, unspecified in relapse
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 elsewhere classified
C95.10	Chronic leukemia of unspecified cell type not having achieved remission
C95.12	Chronic leukemia of unspecified cell type, in relapse
C96.Z	Other specified malignant neoplasms of lymphoid, hematopoietic and related tissue
D45	Polycythemia vera
D47.1	Chronic myeloproliferative disease
D47.3	Essential (hemorrhagic) thrombocythemia
D47.4	Osteomyelofibrosis

CODE	DESCRIPTION
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)
D72.828	Other elevated white blood cell count
D72.829	Elevated white blood cell count, unspecified
D72.89	Other specified disorders of white blood cells
D72.9	Disorder of white blood cells, 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
D77	Other disorders of blood and blood-forming organs in diseases classified elsewhere
R16.1	Splenomegaly, not elsewhere classified
R16.2	Hepatomegaly with splenomegaly, not elsewhere classified

Group 15 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 15 Codes: (91 Codes)

CODE	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

CODE	DESCRIPTION
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
C92.90	Myeloid leukemia, unspecified, not having achieved remission
C92.92	Myeloid leukemia, unspecified in relapse
C93.00	Acute monoblastic/monocytic leukemia, not having achieved remission
C93.02	Acute monoblastic/monocytic leukemia, in relapse
C94.00	Acute erythroid leukemia, not having achieved remission
C94.02	Acute erythroid leukemia, in relapse
C94.80	Other specified leukemias not having achieved remission
C94.82	Other specified leukemias, in relapse
C95.00	Acute leukemia of unspecified cell type not having achieved remission
C95.02	Acute leukemia of unspecified cell type, in relapse
C95.90	Leukemia, unspecified not having achieved remission
C95.92	Leukemia, unspecified, in relapse
C96.20	Malignant mast cell neoplasm, unspecified
C96.21	Aggressive systemic mastocytosis
C96.22	Mast cell sarcoma
C96.29	Other malignant mast cell neoplasm
D03.0 - D03.9	Melanoma in situ of lip - Melanoma in situ, unspecified
D47.01	Cutaneous mastocytosis
D47.02	Systemic mastocytosis
D47.09	Other mast cell neoplasms of uncertain behavior
D48.1	Neoplasm of uncertain behavior of connective and other soft tissue
R16.1	Splenomegaly, not elsewhere classified
R16.2	Hepatomegaly with splenomegaly, not elsewhere classified
Z85.820	Personal history of malignant melanoma of skin

Group 16 Paragraph:

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

Group 16 Codes: (40 Codes)

CODE	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 17 Paragraph:

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

Group 17 Codes: (10 Codes)

CODE	DESCRIPTION
C71.0 - C71.9	Malignant neoplasm of cerebrum, except lobes and ventricles - Malignant neoplasm of brain, unspecified

Group 18 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 18 Codes: (40 Codes)

CODE	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

CODE	DESCRIPTION
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 19 Paragraph:

CPT Code 81311 (NRAS) is considered medically necessary for the following ICD-10-CM codes

Group 19 Codes: (23 Codes)

CODE	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 20 Paragraph:

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

Group 20 Codes: (14 Codes)

CODE	DESCRIPTION
C49.A0 - C49.A9	Gastrointestinal stromal tumor, unspecified site - Gastrointestinal stromal tumor of other sites
C92.10 - C92.12	Chronic myeloid leukemia, BCR/ABL-positive, not having achieved remission - Chronic myeloid leukemia, BCR/ABL-positive, in relapse

CODE	DESCRIPTION
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 21 Paragraph:

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

Group 21 Codes: (1 Code)

CODE	DESCRIPTION
E88.01	Alpha-1-antitrypsin deficiency

Group 22 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 22 Codes: (23 Codes)

CODE	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
C96.20	Malignant mast cell neoplasm, unspecified
C96.21	Aggressive systemic mastocytosis
C96.22	Mast cell sarcoma
C96.29	Other malignant mast cell neoplasm
D47.01	Cutaneous mastocytosis
D47.02	Systemic mastocytosis
D47.09	Other mast cell neoplasms of uncertain behavior
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

CODE	DESCRIPTION
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 Paragraph:

CPT code 81168 CCND1/IGH is considered medically necessary for patients who have non- Hodgkin's lymphoma.

Group 23 Codes: (40 Codes)

CODE	DESCRIPTION
C85.10 - C85.99	Unspecified B-cell lymphoma, unspecified site - Non-Hodgkin lymphoma, unspecified, extranodal and solid organ sites

Group 24 Paragraph:

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

Group 24 Codes: (6 Codes)

CODE	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
D35.1	Benign neoplasm of parathyroid gland

Group 25 Paragraph:

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

Group 25 Codes: (1 Code)

CODE	DESCRIPTION
E83.01	Wilson's disease

Group 26 Paragraph:

CPT codes 81518, 81519, 81522, 81523 (Oncology, breast mRNA) and CPT 81520 Prosigna® Breast Cancer

Prognostic Gene Signature Assay are considered medically necessary for the following ICD-10-CM codes:

Group 26 Codes: (67 Codes)

CODE	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

CODE	DESCRIPTION
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
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

CODE	DESCRIPTION
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 27 Paragraph:

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

Group 27 Codes: (2 Codes)

CODE	DESCRIPTION
Z48.21	Encounter for aftercare following heart transplant
Z94.1	Heart transplant status

Group 28 Paragraph:

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

Group 28 Codes: (28 Codes)

CODE	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

CODE	DESCRIPTION
C92.Z2	Other myeloid leukemia, in relapse
C92.90	Myeloid leukemia, unspecified, not having achieved remission
C92.92	Myeloid leukemia, unspecified in relapse
C93.00	Acute monoblastic/monocytic leukemia, not having achieved remission
C93.02	Acute monoblastic/monocytic leukemia, in relapse
C94.00	Acute erythroid leukemia, not having achieved remission
C94.02	Acute erythroid leukemia, in relapse
C94.80	Other specified leukemias not having achieved remission
C94.82	Other specified leukemias, in relapse
C95.00	Acute leukemia of unspecified cell type not having achieved remission
C95.02	Acute leukemia of unspecified cell type, in relapse
C95.90	Leukemia, unspecified not having achieved remission
C95.92	Leukemia, unspecified, in relapse
R16.1	Splenomegaly, not elsewhere classified
R16.2	Hepatomegaly with splenomegaly, not elsewhere classified

Group 29 Paragraph:

CPT codes 81352 TP53 (tumor protein 53) (e.g. tumor samples), targeted sequence analysis of 2-5 exons, and CPT code 81351 TP53 (tumor protein 53) (e.g. Li-Fraumeni syndrome, tumor samples), full gene sequence or targeted sequence analysis of >5 exons are considered medically necessary for the following ICD-10-CM codes

Group 29 Codes: (81 Codes)

CODE	DESCRIPTION
C88.8	Other malignant immunoproliferative diseases
C92.00	Acute myeloblastic leukemia, not having achieved remission
C92.02	Acute myeloblastic leukemia, in relapse
C92.20	Atypical chronic myeloid leukemia, BCR/ABL-negative, not having achieved remission
C92.22	Atypical chronic myeloid leukemia, BCR/ABL-negative, 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

CODE	DESCRIPTION
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
C92.90	Myeloid leukemia, unspecified, not having achieved remission
C92.92	Myeloid leukemia, unspecified in relapse
C93.00	Acute monoblastic/monocytic leukemia, not having achieved remission
C93.02	Acute monoblastic/monocytic leukemia, in relapse
C93.10	Chronic myelomonocytic leukemia not having achieved remission
C93.12	Chronic myelomonocytic leukemia, in relapse
C93.Z0	Other monocytic leukemia, not having achieved remission
C93.Z2	Other monocytic leukemia, in relapse
C93.90	Monocytic leukemia, unspecified, not having achieved remission
C93.92	Monocytic leukemia, unspecified in relapse
C94.00	Acute erythroid leukemia, not having achieved remission
C94.02	Acute erythroid leukemia, in relapse
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 elsewhere classified
C94.80	Other specified leukemias not having achieved remission
C94.82	Other specified leukemias, in relapse
C95.00	Acute leukemia of unspecified cell type not having achieved remission
C95.02	Acute leukemia of unspecified cell type, in relapse
C95.10	Chronic leukemia of unspecified cell type not having achieved remission
C95.12	Chronic leukemia of unspecified cell type, in relapse
C95.90	Leukemia, unspecified not having achieved remission
C95.92	Leukemia, unspecified, in relapse

CODE	DESCRIPTION
C96.Z	Other specified malignant neoplasms of lymphoid, hematopoietic and related tissue
C96.9	Malignant neoplasm of lymphoid, hematopoietic and related tissue, unspecified
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
D61.818	Other pancytopenia
D69.49	Other primary thrombocytopenia
D69.6	Thrombocytopenia, unspecified
D69.8	Other specified hemorrhagic conditions
D69.9	Hemorrhagic condition, unspecified
D70.8	Other neutropenia
D70.9	Neutropenia, unspecified
D72.810	Lymphocytopenia
D72.818	Other decreased white blood cell count
D72.819	Decreased white blood cell count, unspecified
D72.821	Monocytosis (symptomatic)

CODE	DESCRIPTION
D72.828	Other elevated white blood cell count
D72.829	Elevated white blood cell count, unspecified
D72.89	Other specified disorders of white blood cells
D72.9	Disorder of white blood cells, unspecified
D75.81	Myelofibrosis
D75.89	Other specified diseases of blood and blood-forming organs
D75.9	Disease of blood and blood-forming organs, unspecified
D77	Other disorders of blood and blood-forming organs in diseases classified elsewhere
R16.1	Splenomegaly, not elsewhere classified
R16.2	Hepatomegaly with splenomegaly, not elsewhere classified

Group 30 Paragraph:

CPT code 81335 TPMT gene is considered medically necessary for the following ICD-10-CM codes:

Group 30 Codes: (12 Codes)

CODE	DESCRIPTION
C91.00 - C91.02	Acute lymphoblastic leukemia not having achieved remission - Acute lymphoblastic leukemia, in relapse
C91.12	Chronic lymphocytic leukemia of B-cell type in relapse
C91.30	Prolymphocytic leukemia of B-cell type not having achieved remission
C91.40	Hairy cell leukemia not having achieved remission
C91.50	Adult T-cell lymphoma/leukemia (HTLV-1-associated) not having achieved remission
C91.60	Prolymphocytic leukemia of T-cell type not having achieved remission
C91.A0	Mature B-cell leukemia Burkitt-type not having achieved remission
C91.Z0	Other lymphoid leukemia not having achieved remission
K50.00	Crohn's disease of small intestine without complications
Z94.84	Stem cells transplant status

Group 31 Paragraph:

CPT code 81334 RUNX1 gene is considered medically necessary for the following ICD-10-CM codes:

Group 31 Codes: (63 Codes)

CODE	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
C92.90	Myeloid leukemia, unspecified, not having achieved remission
C92.92	Myeloid leukemia, unspecified in relapse
C93.00	Acute monoblastic/monocytic leukemia, not having achieved remission
C93.02	Acute monoblastic/monocytic leukemia, in relapse
C93.10	Chronic myelomonocytic leukemia not having achieved remission
C93.12	Chronic myelomonocytic leukemia, in relapse
C93.Z0	Other monocytic leukemia, not having achieved remission
C93.Z2	Other monocytic leukemia, in relapse
C93.90	Monocytic leukemia, unspecified, not having achieved remission
C93.92	Monocytic leukemia, unspecified in relapse
C94.00	Acute erythroid leukemia, not having achieved remission
C94.02	Acute erythroid leukemia, in relapse
C94.6	Myelodysplastic disease, not elsewhere classified
C94.80	Other specified leukemias not having achieved remission
C94.82	Other specified leukemias, in relapse
C95.00	Acute leukemia of unspecified cell type not having achieved remission
C95.02	Acute leukemia of unspecified cell type, in relapse
C95.10	Chronic leukemia of unspecified cell type not having achieved remission

CODE	DESCRIPTION
C95.12	Chronic leukemia of unspecified cell type, in relapse
C95.90	Leukemia, unspecified not having achieved remission
C95.92	Leukemia, unspecified, in relapse
C96.Z	Other specified malignant neoplasms of lymphoid, hematopoietic and related tissue
C96.9	Malignant neoplasm of lymphoid, hematopoietic and related tissue, unspecified
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
D61.818	Other pancytopenia
D69.49	Other primary thrombocytopenia
D69.6	Thrombocytopenia, unspecified
D69.8	Other specified hemorrhagic conditions
D69.9	Hemorrhagic condition, unspecified
D70.8	Other neutropenia
D70.9	Neutropenia, unspecified
D72.810	Lymphocytopenia
D72.818	Other decreased white blood cell count
D72.819	Decreased white blood cell count, unspecified
D75.89	Other specified diseases of blood and blood-forming organs
D75.9	Disease of blood and blood-forming organs, unspecified
D77	Other disorders of blood and blood-forming organs in diseases classified elsewhere
R16.1	Splenomegaly, not elsewhere classified
R16.2	Hepatomegaly with splenomegaly, not elsewhere classified

Group 32 Paragraph:

CPT codes 81175-81176-ASXL1 gene is considered medically necessary for the following ICD-10-CM codes:

Group 32 Codes: (81 Codes)

CODE	DESCRIPTION
C88.8	Other malignant immunoproliferative diseases
C92.00	Acute myeloblastic leukemia, not having achieved remission
C92.02	Acute myeloblastic leukemia, in relapse
C92.20	Atypical chronic myeloid leukemia, BCR/ABL-negative, not having achieved remission
C92.22	Atypical chronic myeloid leukemia, BCR/ABL-negative, 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
C92.90	Myeloid leukemia, unspecified, not having achieved remission
C92.92	Myeloid leukemia, unspecified in relapse
C93.00	Acute monoblastic/monocytic leukemia, not having achieved remission
C93.02	Acute monoblastic/monocytic leukemia, in relapse
C93.10	Chronic myelomonocytic leukemia not having achieved remission
C93.12	Chronic myelomonocytic leukemia, in relapse
C93.Z0	Other monocytic leukemia, not having achieved remission
C93.Z2	Other monocytic leukemia, in relapse
C93.90	Monocytic leukemia, unspecified, not having achieved remission
C93.92	Monocytic leukemia, unspecified in relapse
C94.00	Acute erythroid leukemia, not having achieved remission

CODE	DESCRIPTION
C94.02	Acute erythroid leukemia, in relapse
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 elsewhere classified
C94.80	Other specified leukemias not having achieved remission
C94.82	Other specified leukemias, in relapse
C95.00	Acute leukemia of unspecified cell type not having achieved remission
C95.02	Acute leukemia of unspecified cell type, in relapse
C95.10	Chronic leukemia of unspecified cell type not having achieved remission
C95.12	Chronic leukemia of unspecified cell type, in relapse
C95.90	Leukemia, unspecified not having achieved remission
C95.92	Leukemia, unspecified, in relapse
C96.Z	Other specified malignant neoplasms of lymphoid, hematopoietic and related tissue
C96.9	Malignant neoplasm of lymphoid, hematopoietic and related tissue, unspecified
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

CODE	DESCRIPTION
D47.9	Neoplasm of uncertain behavior of lymphoid, hematopoietic and related tissue, unspecified
D61.818	Other pancytopenia
D69.49	Other primary thrombocytopenia
D69.6	Thrombocytopenia, unspecified
D69.8	Other specified hemorrhagic conditions
D69.9	Hemorrhagic condition, unspecified
D70.8	Other neutropenia
D70.9	Neutropenia, unspecified
D72.810	Lymphocytopenia
D72.818	Other decreased white blood cell count
D72.819	Decreased white blood cell count, unspecified
D72.821	Monocytosis (symptomatic)
D72.828	Other elevated white blood cell count
D72.829	Elevated white blood cell count, unspecified
D72.89	Other specified disorders of white blood cells
D72.9	Disorder of white blood cells, unspecified
D75.81	Myelofibrosis
D75.89	Other specified diseases of blood and blood-forming organs
D75.9	Disease of blood and blood-forming organs, unspecified
D77	Other disorders of blood and blood-forming organs in diseases classified elsewhere
R16.1	Splenomegaly, not elsewhere classified
R16.2	Hepatomegaly with splenomegaly, not elsewhere classified

Group 33 Paragraph:

CPT codes 81120-81121, IDH1 and IDH2, are considered medically necessary for the following ICD-10-CM codes:

CPT code 81345, TERT, is considered medically necessary for C71.0-C71.9 only.

Group 33 Codes: (68 Codes)

CODE	DESCRIPTION
C71.0 - C71.9	Malignant neoplasm of cerebrum, except lobes and ventricles - Malignant neoplasm of brain, unspecified

CODE	DESCRIPTION
C88.8	Other malignant immunoproliferative diseases
C92.00	Acute myeloblastic leukemia, not having achieved remission
C92.02	Acute myeloblastic leukemia, in relapse
C92.20	Atypical chronic myeloid leukemia, BCR/ABL-negative, not having achieved remission
C92.22	Atypical chronic myeloid leukemia, BCR/ABL-negative, 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
C92.90	Myeloid leukemia, unspecified, not having achieved remission
C92.92	Myeloid leukemia, unspecified in relapse
C93.00	Acute monoblastic/monocytic leukemia, not having achieved remission
C93.02	Acute monoblastic/monocytic leukemia, in relapse
C93.10	Chronic myelomonocytic leukemia not having achieved remission
C93.12	Chronic myelomonocytic leukemia, in relapse
C93.Z0	Other monocytic leukemia, not having achieved remission
C93.Z2	Other monocytic leukemia, in relapse
C93.90	Monocytic leukemia, unspecified, not having achieved remission
C93.92	Monocytic leukemia, unspecified in relapse
C94.00	Acute erythroid leukemia, not having achieved remission
C94.02	Acute erythroid leukemia, in relapse
C94.40	Acute panmyelosis with myelofibrosis not having achieved remission
C94.41	Acute panmyelosis with myelofibrosis, in remission

CODE	DESCRIPTION
C94.42	Acute panmyelosis with myelofibrosis, in relapse
C94.80	Other specified leukemias not having achieved remission
C94.82	Other specified leukemias, in relapse
C95.00	Acute leukemia of unspecified cell type not having achieved remission
C95.02	Acute leukemia of unspecified cell type, in relapse
C95.10	Chronic leukemia of unspecified cell type not having achieved remission
C95.12	Chronic leukemia of unspecified cell type, in relapse
C95.90	Leukemia, unspecified not having achieved remission
C95.92	Leukemia, unspecified, in relapse
C96.Z	Other specified malignant neoplasms of lymphoid, hematopoietic and related tissue
D45	Polycythemia vera
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)
D72.828	Other elevated white blood cell count
D72.829	Elevated white blood cell count, unspecified
D72.89	Other specified disorders of white blood cells
D72.9	Disorder of white blood cells, unspecified
D75.81	Myelofibrosis
D75.89	Other specified diseases of blood and blood-forming organs
D75.9	Disease of blood and blood-forming organs, unspecified
D77	Other disorders of blood and blood-forming organs in diseases classified elsewhere
R16.1	Splenomegaly, not elsewhere classified
R16.2	Hepatomegaly with splenomegaly, not elsewhere classified

Group 34 Paragraph:

CPT code 81305 MYD88 is considered medically necessary for the following ICD-10-CM codes:

Group 34 Codes: (21 Codes)

CODE	DESCRIPTION
C83.00 - C83.09	Small cell B-cell lymphoma, unspecified site - Small cell B-cell lymphoma, extranodal and solid organ sites
C85.80 - C85.89	Other specified types of non-Hodgkin lymphoma, unspecified site - Other specified types of non-Hodgkin lymphoma, extranodal and solid organ sites
C88.0	Waldenstrom macroglobulinemia

Group 35 Paragraph:

Use CPT code 81227 CYP2C9 for individuals who have relapsing forms of multiple sclerosis. The following ICD-10-CM diagnosis code is effective for services rendered on or after July 1. 2020.

Group 35 Codes: (1 Code)

CODE	DESCRIPTION
G35	Multiple sclerosis

ICD-10-CM 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: (9 Codes)

CODE	DESCRIPTION
Z13.71	Encounter for nonprocreative screening for genetic disease carrier status
Z13.79	Encounter for other screening for genetic and chromosomal anomalies
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 procreative genetic counseling
Z36.0	Encounter for antenatal screening for chromosomal anomalies

ICD-10-PCS Codes

N/A

Additional ICD-10 Information

N/A

Bill Type Codes

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

N/A

Revenue Codes

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

N/A

Other Coding Information

N/A

Revision History Information

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION
10/01/2022	R18	Due to the annual ICD-10-CM code update, the following codes had descriptor changes occur in the ICD-10-CM section that supports Medical Necessity.: C94.6 descriptor was changed in Group 14; C94.6 descriptor was changed in Group 29; C94.6 descriptor was changed in Group 31; C94.6 descriptor was changed in Group 32.
05/01/2022	R17	5/1/2022 Correction: ICD-10-CM diagnosis code, C56.3 is effective for services rendered on or after 10/1/2021,

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION
05/01/2022	R16	Added ICD-10-CM diagnosis code C56.3 to the "ICD-10-CM Codes that Support Medical Necessity" section- Group1, effective for services rendered on or after 5/1/2022.
04/01/2022	R15	The following, underlined language was added to the Correct Coding of Molecular Testing Panels under Specific Coding of Molecular Testing Panels in the Article text: CPT code 81455 should be billed when 51 or greater genes are ordered for molecular biomarkers. Please refer to Local Coverage Determination L37810 Genomic Sequence Analysis Panels in the Treatment of Solid Organ Neoplasms and the associated Article A56867 CPT code 81455 was removed from CPT/HCPCS Code section-Group 3.
01/01/2022	R14	Due to the annual CPT/HCPCS code update, CPT code 81523 was added to the CPT/HCPCS Codes section- Group 1, and CPT code 81349 was added to the CPT/HCPCS Codes section- Group 3. CPT codes 81522 and 81523 were added to the "ICD-10-CM Codes that Support Medical Necessity" section- Group 26 paragraph, effective for services rendered on or after 1/1/2022.
11/30/2021	R13	CPT code 81546 was deleted from CPT/HCPCS Codes section- Group 2. Please refer to LCD L38968 Thyroid Nodule Molecular Testing and Billing and Coding Article A58656.
05/15/2021	R12	-The following clarifying guidance which was published on our website on 7/29/2021 regarding the Correct Coding of Molecular Testing Panels was added under Specific Coding of Molecular Testing Panels in the Article text above: The submission of claims using individual gene CPT codes, when either 5-50 or >50 gene panels are ordered, is considered incorrect coding. Correct coding requires that when a panel code is ordered, it should be billed, rather than the individual gene codes. CPT code 81445 or 81450 should be billed when 5 to 50 genes are ordered. CPT code 81455 should be billed when 51 or greater genes are ordered for molecular biomarkers. When a panel with greater than one or less than five genes is ordered, use the corresponding existing panel CPT code or CPT code 81479 if none exists. -The following note was added to the CPT/HCPCS Section paragraph- Group 4:

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION
		Note: When a panel with greater than one or less than five genes is ordered, use the corresponding existing panel CPT code or CPT code 81479 if none exists.
05/15/2021	R11	Added CPT code 81353 which had been inadvertently omitted to CPT/HCPCS Code section-Group2, effective January 1, 2021. Deleted SCA1 CPT code 81479 from the CPT/HCPCS code section- Group 4 Paragraph, Tier 2/NOC Non-covered Code/Gene Combinations, due to the inadvertent inclusion of SCA1 as a gene in error. Added PLA code 0070U to the ICD-10-CM Diagnosis Codes That Support Medical Necessity and to the Paragraph, Group 9, effective May 15, 2021 Added PLA code 0070U to CPT/HCPCS Code Section- Group 1, effective May 15, 2021
04/01/2021	R10	Added Proprietary Laboratory Analysis (PLA) code 0027U to the coding information section.: **CPT Codes 81279** JAK2 (Janus kinase 2) (eg, myeloproliferative disorder), (exon 12 sequence and exon 13 sequence) and **0027U** (Janus kinase 2) (e.g., myeloproliferative disorder), gene analysis, targeted sequence analysis exons 12-15 are 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. Added PLA code 0027U to the CPT/HCPCS Code section-Group 1. Added PLA code 0027U to the ICD-10-CM Diagnosis Codes That Support Medical Necessity section-Group 14.
01/01/2021	R9	Due to the HCPCS update, effective 1/1/2021, the following CPT codes were added to the Group 1 tabular CPT code listing: 81168, 81338, 81339, 81347, 81348, 81351, 81352 and removed from the Group 1 paragraph section. Due to the HCPCS update, effective 1/1/2021, the following CPT codes were added to the Group 2 tabular code listing: 81191, 81192, 81193, 81194, 81353, 81357, 81419, 81529, 81546, 81554, and 81360 and removed from the Group 2 paragraph section. Due to the annual HCPCS update, CPT code 81545 was deleted from Group 3, effective 1/1/2021:

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION
01/01/2021	R8	**<u>The Indications of Coverage by CPT code section was revised as follows</u>**: CPT Code 81401 was replaced by CPT codes (81168) CCND1/IGH;(81278) BCL1/IgH, t CPT Code 81402 was replaced by CPT code (81338) MPL CPT Code 81403 was replaced by CPT code 81339) MPL CPT Code 81403 was replaced by CPT code (81279) JAK2 CPT code 81404 was replaced by CPT code (81352) TP53, and CPT code 81405 was replaced by CPT code (81351) TP53 CPT code 81479 was replaced by CPT code (81347) RARS **<u>The CPT/HCPCS Codes Section was revised as follows:</u>** **Group 1 Tier 1 Covered Codes:** Added CPT codes 81168, 81338, 81339, 81347, 81348, 81351, 81352. **Group 2 Tier 1 Individual Review Codes:** Added CPT codes 81191, 81192, 81193, 81194, 81353, 81357, 81419, 81529, 81546, 81554, 81360. **Group 4 Tier 2 CPT and NOC Codes:** CPT code 81401 CND1/IGH was replaced by 81168-now in Group 1; CPT code 81405 TP53 was replaced by 81353- now in Group 2 ; CPT code 81479 RARS was replaced by 81347- now in Group 1. **<u>ICD-10 Codes that Support Medical Necessity Section was revised as follows</u>** **Group 14: Paragraph:** CPT codes Deleted code 81402 MPL was replaced by 81338; 81403 MPL was replaced by 81339, and 81403 JAK2 was replaced by 81279. **Group 23: Paragraph:** CPT code 81401 CCND1/IGH was replaced by 81168. **Group 29: Paragraph:** CPT codes 81404 TP53 was replaced by 81352; CPT code 81405 TP53 was replaced by 81351.

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION
07/01/2020	R7	Deleted 81227 from the CPT/HCPCS section Group 3 and added CPT code 81227 to the "CPT/HCPCS section" Group 1. Added 81227 to the "ICD-10-CM that support Medically Necessity section-Group 35 Added the following explanatory language to the Article Text: Use 81227 for CYP2C9 genotyping for individuals who have a relapsing form of multiple sclerosis, and require CYP2C9 genotyping for dosing in accordance with the FDA prescribing information for Mayzent. CYP2C9 testing must include the *1, *2, and *3 alleles that are necessary to safely dose the FDA-approved drug Mayzent.
01/01/2020	R6	The following wording for CPT code 81445 was corrected: "please refer to LCD L36376" was revised to read "please refer to L37810".
01/01/2020	R5	Due to the annual CPT/HCPCS code update, CPT codes 81307-81309, 81522, and 81552 have been added to Group1- Tier 1 Covered Codes. CPT codes 81277 and 81542 have been added to CPT/HCPCS Codes Group2- Individual Review, effective for services rendered on or after January 1, 2020. The following Revision History language, effective for services rendered on or after 1/1/2019, was relocated from the Article Text section to the Revision History section: **" Annual CPT/HCPCS Revisions Effective 1/1/2019** Due to the annual CPT/HCPCS Code update and transition of coding guidance to this article, the following codes have been deleted from Group 1 in LCD L35000: CPT codes 81211, and 81213 have been deleted- to report see CPT code(s) 81162, 81163, 81164; CPT code 81214 has been deleted- to report see CPT codes 81165, 81166. Due to the annual new CPT/HCPCS Code update and transition of coding guidance to this article, the following new 2019 CPT codes have been added to The CPT/HCPCS section -Group 2 which will require individual review: CPT codes 81177, 81178, 81179, 81180, 81181, 81182, 81183, 81184, 81185, 81186, 81187, 81188, 81189, 81190, 81233, 81306, 81312, 81320, 81333, 81343, 81344.

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION
		Due to the annual new CPT/HCPCS Code update and transition of coding guidance to this article, the following new Tier 1, 2019 CPT codes replaced existing Tier 2 Non-covered codes and have been added to the CPT/HCPCS section- Group 3: CPT codes 81171, 81172, 81173, 81174, 81204, 81234, 81239, 81271, 81274, 81284, 81285, 81286, 81289, 81329, 81336, and 81337. CPT code 81443 was added to CPT/HCPCS section- Group 3 because it is considered screening and is not covered. Due to the annual new CPT/HCPCS Code update and transition of coding guidance to this article, the following new Tier 1, 2019 CPT codes 81305, and 81518 replaced existing Tier 2 Covered codes and were added to CPT/HCPCS section- Group 1. CPT codes 81236, 81237, and 81345 were added to CPT/HCPCS Group 1 due to prior existing coverage. CPT code 81518 was added to ICD10-CM That Supports Medical Necessity section - Group 26. CPT code 81305 replaced 81479 and was added to ICD10-CM That Supports Medical Necessity section -Group 34. CPT codes 81163, 81164, 81165, 81166, and 81167 were added to ICD10-CM That Supports Medical Necessity section -Group 1. CPT code 81345 was added to ICD10-CM That Supports Medical Necessity section - Group 33."
10/15/2019	R4	Added ICD-10-CM diagnosis code D45 to the "ICD-10 Codes that Support Medical Necessity" section-Group 14, effective for services rendered on or after 10/15/2019.
10/03/2019	R3	This article was converted to the new Billing and Coding Article type. Bill types and Revenue codes have been removed from this article. Guidance on these codes is available in the Bill type and Revenue code sections.
08/15/2019	R2	The title has been changed from "Molecular Pathology Procedures- Related to Molecular Policy Procedures LCD (L35000)" to Billing and Coding: Molecular Pathology Procedures.
01/01/2019	R1	Corrected URL.

Associated Documents

Related Local Coverage Documents

LCDs

L35000 - Molecular Pathology Procedures

Related National Coverage Documents

N/A

Statutory Requirements URLs

Title XVIII of the Social Security Act (SSA)
Description 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.
Title XVIII of the Social Security Act (SSA)
Description Section 1833(e) prohibits Medicare payment for any claim which lacks the necessary information to process the claim.
Title XVIII of the Social Security Act (SSA)
Description Section 1862(a)(7) excludes routine physical examinations, unless otherwise covered by statute.
Code of Federal Regulations42 CFR, Section 410.32
Description Indicates that diagnostic tests may only be ordered by the treating physician

Rules and Regulations URLs

N/A

CMS Manual Explanations URLs

CMS Publication 100-02, Medicare Benefit Policy Manual, Chapter 15, Section 80.1
Description Laboratory services must meet applicable requirements of CLIA
CMS Publication 100-04, Medicare Claims Processing Manual, Chapter 16, Section 40.7
Description 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
Description Advance Beneficiary Notice of Noncoverage (ABN)
CMS Publication 100-08, Medicare Program Integrity Manual, Chapter 13
Description Local Coverage Determinations
CMS National Correct Coding Initiative (NCCI) Policy Manual for Medicare Services, Chapter 10, Pathology/Laboratory Services, (A)
Description Introduction
CMS Publication 100-02, Medicare Benefit Policy Manual, Chapter 15, Section 80.6. 5
Description Describes the Surgical/Cytopathology Exception.
CMS National Correct Coding Initiative (NCCI) Policy Manual for Medicare Services, Chapter 10 Pathology/Laboratory Services
Description Addresses reflex testing

Other URLs

N/A

Public Versions

UPDATED ON	EFFECTIVE DATES	STATUS
09/19/2022	10/01/2022 - N/A	Currently in Effect (This Version)

UPDATED ON	EFFECTIVE DATES	STATUS
07/05/2022	05/01/2022 - 09/30/2022	Superseded
04/18/2022	05/01/2022 - N/A	Superseded
03/23/2022	04/01/2022 - 04/30/2022	Superseded
12/22/2021	01/01/2022 - 03/31/2022	Superseded
12/02/2021	11/30/2021 - 12/31/2021	Superseded
09/21/2021	05/15/2021 - 11/29/2021	Superseded
04/22/2021	05/15/2021 - N/A	Superseded
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Keywords

N/A