

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

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Contractor Information

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATE(S)
National Government Services, Inc.	MAC - Part A	06101 - MAC A	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, Inc.	A and B and HHH MAC	14212 - MAC B	J - K	Massachusetts

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATE(S)
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

LCD Information

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CMS National Coverage Policy

N/A

Coverage Guidance

Coverage Indications, Limitations, and/or Medical Necessity

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.

This Local Coverage Determination (LCD) addresses the circumstances under which the item or service may be reasonable and necessary. For laboratory services, a service may be reasonable and necessary if the service is safe and effective; and appropriate, including the duration and frequency that is considered appropriate for the item or service, in terms of whether it is furnished in accordance with accepted standards of medical practice for the diagnosis of the patient's condition; furnished in a setting appropriate to the patient's medical needs and condition; ordered and furnished by qualified personnel; one that meets, but does not exceed, the patient's medical need; and is at least as beneficial as an existing and available medically appropriate alternative.

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

This LCD gives general guidance to the medically reasonable and necessary applications of the Molecular Pathology Procedures and Genomic Sequencing Procedures, described in Current Procedural Terminology (CPT). Coding guidance is provided in **Molecular Pathology Procedures Article A56199**, attached below.

Indications:

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

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

Limitations:

- Any procedures required prior to cell lysis should be reported separately and utilization must be clearly supported based on the application and clinical utility. Such claims may be subject to prepayment medical review.
- The medically necessary interpretation and report of a molecular pathology test, written by a pathologist, which is above and beyond the report of standard laboratory results may not be reported by Non- physician practitioners (e.g., PhD, scientists etc.); only physicians are eligible to report this service.
- Testing for quality assurance component of the service is not separately billable.

Indications and Limitations of Coverage

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 lymphoblastic leukemia (ALL) and chronic myeloid leukemia (CML) to guide therapeutic decision making.

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

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.

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.

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.

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.

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.

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.

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).

CCND1/IGH (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.

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.

Chimerism analysis to identify appropriate donors and monitor engraftment success or disease reoccurrence is considered medically necessary.

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

CYP2C9 (cytochrome P450, family 2, subfamily D polypeptide 9) (e.g., drug metabolism), gene analysis, is only considered medically necessary for individuals who have relapsing forms 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.

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 CerdelgaTM (eliglustat) for Gaucher's disease.

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®]).

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.

FLT3 is considered medically necessary in patients with acute myeloid leukemia (AML) to guide therapeutic decision making.

Gene Testing for Warfarin Response Pharmacogenomic Testing for Warfarin Response, gene testing on **CYP2C9** and/or **VKORC1** see NCD 90.1 for coverage information.

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.

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.

HUMAN PLATELET ANTIGEN 1-15 as genotyping for human platelet antigens is important for identifying woman at risk for neonatal alloimmune thrombocytopenia (NAIT). Post-transfusion purpura is an immune reaction against human platelet antigens, often occurring when a woman is sensitized during pregnancy, then subsequently receives a transfusion. There are few Medicare beneficiaries for whom this testing will be clinically actionable.

IGH@ (Immunoglobulin heavy chain locus) is considered medically necessary for acute lymphoblastic leukemia (ALL) and lymphoma, B-cell to guide therapeutic decision making.

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.

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

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.

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.

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.

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.

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.

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.

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.

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).

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).

MTHFR (5,10-methylenetetrahydrofolate 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.

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.

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.

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

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.

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.

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.

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.

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.

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

RARS (SF3B1 mutation) is considered medically necessary in patients with Myelodysplastic Syndrome to guide therapeutic decision-making.

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.

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.

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.

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

TP53 (tumor protein 53) (e.g. tumor samples), targeted sequence analysis of 2-5 exons, and CPT code 81405 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 Myeloplasic Disease to guide therapeutic decision-making.

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.

Tier 2 Covered Gene/Gene Combinations

Limited coverage may be provided for specific genes reported below:

ACE
ATP7B (ATPase, Cu++ transporting, beta polypeptide)
CCND1/IGH
CBFB-MYH11
CDKN2A (cyclin-dependent kinase inhibitor 2A)
E2A/PBX1
EML4-ALK
ETV6-RUNX1
EWSR1/ERG
EWSR1/FLI1
EWSR1/WT1
F11coagulation factor XI
F13B
F5
F7
F8 (coagulation factor VIII)
FGB
FIP1L1-PDGFR
FOXO1/PAX3
FOXO1/PAX7
MEN1 (multiple endocrine neoplasia 1) (eg, multiple endocrine neoplasia type 1, Wermer syndrome), duplication/deletion
MEN1 (multiple endocrine neoplasia 1) (eg, multiple endocrine neoplasia type 1, Wermer syndrome), full gene sequence
MUTYH (mutY homolog [E.coli])
NPM/ALK
PAX8/PPARG
PRSS1 (protease, serine, 1 [trypsin 1])
RARS (SF3B1
RUNX1/RUNX1T1
TP53 (tumor protein 53) (e.g. tumor samples), targeted sequence analysis of 2-5 exons
TP53 (tumor protein 53) (e.g. Li-Fraumeni syndrome, tumor samples), full gene sequence or targeted sequence analysis of >5 exons
VHL (von Hippel-Lindau tumor suppressor)

Tier 2 Individual Review Codes/Gene Combinations

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

Tier 2 Non-covered Codes/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 policy):

ABCC8

ACADM
ACADS (acyl-CoA dehydrogenase)
ACADVL (acyl-CoA dehydrogenase, very long chain)
ADRB2
AGTR1
AIRE (APSI)
AKT1
ANG (angiogenin, ribonuclease, RNase A family, 5)
APOE
AQP2 (aquaporin 2 [collecting duct])
AR (androgen receptor)
ARX (aristaless related homeobox)
ATN1
BTD (biotinidase)
C9orf72
CASR (CAR, EIG8, extracellular calcium-sensing receptor, FHH, FIH, GPRC2A, HHC, HHC1, NSHPT, PCAR1)
CAV3 (caveolin 3) (eg, CAV3-related distal myopathy, limb-girdle muscular dystrophy type 1C), full gene sequence
CBS (cystathionine-beta-synthase)
CCR5
CDKL5 (cyclin-dependent kinase-like 5)
CFH/ARMS2
Chromosome 18q-
CLRN1
CLRN1 (clarin 1)
CYP1B1 (cytochrome P450, family 1, subfamily B, polypeptide 1)
CYP21A2 (cytochrome P450, family 21, subfamily A, polypeptide2)
CYP21A2
DEK/NUP214
DLAT (dihydrolipoamide S-acetyltransferase)
DLD (dihydrolipoamide dehydrogenase)
DMPK (dystrophia myotonica-protein kinase (DM gene and DM1)
DMPK (dystrophia myotonica-protein kinase)
DYT1 (TOR1A)
EGR2 (early growth response 2) (eg, Charcot-Marie-Tooth)
F8 (coagulation factor VIII)
F8 (coagulation factor VIII)
FGFR2 (fibroblast growth factor receptor 2) (2 EXONS)
FGFR3
FGFR3
FGFR3 (fibroblast growth factor receptor 3) (4 EXONS)
FGFR3 (fibroblast growth factor receptor 3) one exon
FKRP (Fukutin related protein)
FOXG1 (forkhead box G1)
FSHMD1A (facioscapulohumeral muscular dystrophy 1A)
FSHMD1A (facioscapulohumeral muscular dystrophy 1A)
FXN (frataxin)
GALT (galactose-1-phosphate uridylyltransferase)
GALT (galactose-1-phosphate uridylyltransferase)
GJB1 (gap junction protein, beta 1) (eg, Charcot-Marie-Tooth X-linked), full gene sequence
H19

HADHA (hydroxyacyl-CoA dehydrogenase/3-ketoacyl-CoA thiolase/enoyl-CoA hydratase [trifunctional protein] alpha subunit)

HAX1 (HAX1_HUMAN, HCLS1-associated protein X-1, HCLSBP1, HS1-associating protein X-1, HS1 binding protein, HS1-binding protein, HS1BP1, HSP1BP-1)

HEXA (hexosaminidase A, alpha polypeptide)

HNF1B (HNF1 homeobox B)

HRAS (v-Ha-ras Harvey rat sarcoma viral oncogene homolog Costello syndrome)

HRAS (v-Ha-ras Harvey rat sarcoma viral oncogene homolog)

HTT (huntingtin)

IL28B

IVD

KCNJ10 (potassium inwardly-rectifying channel, subfamily J, member 10)

KCNQ10T1 (KCNQ1 overlapping transcript 1)

KIF6

Level 8 Molecular Pathology Procedures

Level 9 Molecular Pathology Procedures

LMNA (lamin A/C)

LPA intron 25 genotype

MEFV (Mediterranean fever) (eg, familial Mediterranean fever)

MEG3/DLK1

MEK1

MLH1

MLL/AFF

MPZ (myelin protein zero)

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-RNR1 (mitochondrially encoded 12S RNA)

MT-TK (mitochondrially encoded tRNA lysine)

MT-TL1

MT-TS1

MT-TS1 (mitochondrially encoded tRNA serine 1)

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)

PIK3C, PI3Ks, PI(3)Ks, PI-3Ks

POLG (polymerase [DNA directed], gamma)

PRKAG2 (protein kinase, AMP-activated, gamma 2 non-catalytic subunit)

PRSS1 (protease, serine, 1 [trypsin 1])

PTPN11 (protein tyrosine phosphatase, non-receptor type 11)

RET (ret-proto-oncogene) (eg, Hirschsprung disease), full gene sequence

SCA1

SDA2

SLC25A4 (solute carrier family 25 [mitochondrial carrier; adenine nucleotide translocation])

SLC9A6 (solute carrier family 9 [sodium/hydrogen exchanger] member 6)

SMN1

SMN1 (survival of motor neuron 1, telomeric)

SMN1/SMN2 (survival of motor neuron 1, telomeric/survival of motor neuron 2, centromeric)
SOS1 (son of sevenless homolog 1)
SPG4
TAZ (tafazzin)
TOR1A
TRD
TSC1 (tuberous sclerosis 1)
TSC2 (tuberous sclerosis 2)
UBE3A (ubiquitin protein ligase)
UPD (Uniparental disomy)
VEGFR2 (CD309, FLK1, VEGFR)
VWF (von Willebrand factor)

Summary of Evidence

HUMAN PLATELET ANTIGEN 1-15

Coverage of (HUMAN PLATELET ANTIGEN 1-15) as genotyping for human platelet antigens is important for identifying woman at risk for neonatal alloimmune thrombocytopenia (NAIT). Post-transfusion purpura is an immune reaction against human platelet antigens, often occurring when a woman is sensitized during pregnancy, then subsequently receives a transfusion. There are few Medicare beneficiaries for whom this testing will be clinically actionable.

IFNL3 (IL28B)

Newer treatment regimens are replacing PEG-interferon therapies. Per UpToDate: "Several clinical features that were predictors of response to interferon-based regimens are no longer relevant to combination direct-acting antiviral (DAA) regimens...Polymorphisms in the IL28B gene, which encodes interferon lambda 3, effectively predicted responses to treatment with interferon-based therapies and accounted for a significant proportion of the differential response observed in patients of certain races, such as patients of African descent. In contrast, neither non-CC IL28 genotype nor race has consistently been associated with lower sustained virologic response (SVR) rates in multiple trials and cohort studies of contemporary DAA combination regimens. Although some studies have suggested a limited impact of IL28 genotype or race on SVR rates with DAA regimens, the magnitude of the impact is small when appropriate regimens are used and not sufficient enough to recommend IL28B genotype testing in routine clinical practice."

G6PD

The WHO recommends testing of drugs to predict for risk of hemolysis in G6PD deficient individuals if the drugs are to be prescribed in areas of high prevalence of G6PD deficiency.

Analysis of Evidence

(Rationale for Determination)

HUMAN PLATELET ANTIGEN 1-15

There are too few Medicare beneficiaries that would both be pregnant and at risk for neonatal alloimmune thrombocytopenia to warrant coverage outside of appeal.

IFNL3 (IL28B)

Given that PEG interferon treatment of HCV is becoming obsolete, so is related companion genetic testing. In addition, when used and IL28 testing is negative, there is little evidence that clinicians still do not use the PEG-interferon-alpha-containing regimens despite the unfavorable response genotype. The testing is, therefore, considered not medically necessary.

G6PD

While initial and even confirmatory testing for G6PD deficiency when certain high-risk drugs are used is appropriate, the use of molecular/genetic/DNA methods is not established. General screening, not to be confused with testing immediately before prescription of high-risk drugs, is not a Medicare benefit.

General Information

Associated Information

N/A

Sources of Information

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Revision History Information

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
07/01/2020	R20	Based on a Reconsideration Request, added CYP2C9 testing which is indicated for the treatment of relapsing forms of multiple sclerosis and requires CYP2C9 genotyping for dosing in accordance with the FDA prescribing information. CYP2C9 testing must include the *1, *2, and *3 alleles that are necessary to safely dose the FDA-approved drug Mayzent, effective for services rendered on or after July, 1, 2020.	- Reconsideration Request - Other (FDA Label)
10/03/2019	R19	This LCD was converted to the new "no-codes" format. There has been no change in coverage with this LCD revision.	Revisions Due To Code Removal
01/01/2019	R18	Based on CR10901 and the annual CPT/HCPCS update, coding guidance has been transitioned to the Molecular Pathology Procedures Article A56199. <i>DATE (01/01/2019): At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which</i>	- Provider Education/Guidance - Revisions Due To CPT/HCPCS Code Changes - Other (CR10901)

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
		<i>requires comment and notice. This revision is not a restriction to the coverage determination; and, therefore not all the fields included on the LCD are applicable as noted in this policy.</i>	
10/01/2018	R17	Due to the annual ICD-10-CM update, diagnosis codes C43.11, C43.12, D03.11, and D03.12 were deleted from code ranges C43.0 - C43.9 and D03.0 - D03.9, and the following codes were added to code ranges C43.0 - C43.9 and D03.0 - D03.9 in the "ICD-10 Codes that Support Medical Necessity" section, Group 4 and Group 15: C43.111, C43.112, C43.121, C43.122, D03.111, D03.112, D03.121, D03.122. <i>DATE (10/01/2018): At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; and, therefore not all the fields included on the LCD are applicable as noted in this policy.</i>	Revisions Due To ICD-10-CM Code Changes
09/01/2018	R16	ICD-10-CM Groups 30-34 were established for CPT codes 81120, 81121 (Group 33); 81335 (Group 30); 81175, 81176 (Group 32); 81334 (Group 31); 81479- MYD88 (Group 34). CPT codes 81105-81112 (HUMAN PLATELET ANTIGEN 1-15), 81283 (IFNL3/IL28B) and 81247-81249 (G6PD)- Added language to "Summary of Evidence" and "Analysis of Evidence (Rationale for Determination)". CPT code 81170- Added ICD-10-CM 0codes C91.00-C91.02 to the "ICD-10 Codes that Support Medical Necessity" section- Group 2. Code 81401-Removed MEN from Non-Covered listing in the "Indications and Limitations of Coverage" section. CPT codes 81218 (CEBPA), 81245- 81246 (FLT3), 81272 (KIT), 81310 (NPM1) -Added ICD-10-CM codes C92.90, C92.92, C93.00, C93.02, C94.80, C94.82, C95.00, C95.02, C95.90, C95.92, R16.1, R16.2 to the "ICD-10 Codes that Support Medical Necessity" section- Groups 5, 11, 15, 28.	- Provider Education/Guidance - Reconsideration Request

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
		CPT codes-81270 (JAK2), 81402 (MPL), 81403 (MPL), 81403 (JAK2, exons 12 and 13), and 81219 (CALR)- Corrected ICD-10-CM diagnosis codes by removing D45, D46.0, D46.1, D46.20, D46.21, D46.22, D46.A, D46.B, D46.C, D46.4, D46.Z, and D46.9 from the "ICD-10 Codes that Support Medical Necessity" section and added C88.8, C92.20, C92.22, C93.10, C93.12, C93.90, C93.92, C93.Z0, C93.Z2, C94.40, C94.41, C94.42, C95.10, C95.12, C96.Z, D47.1, D47.3, D47.4, D47.9, D47.Z9, D72.821, D72.828, D72.829, D72.89, D72.9, D75.9, D77, R16.1, R16.2-Group14 CPT code 81314-Added ICD-10-CM codes C49.A0-C49.A9 to "ICD-10 Codes that Support Medical Necessity" section-Group 20. CPT codes 81261-81264-Added ICD-10-CM codes C91.00-C91.02 to the "ICD-10 Codes that Support Medical Necessity" section- Group 13 and corrected the Indication of Coverage criteria by replacing acute lymphoblastic leukemia (AML) with acute lymphoblastic leukemia (ALL). The AML ICD-10-CM codes were removed to correct- Group 13. CPT codes 81206-81208-Added ICD-10-CM codes C91.00-C91.02 to the "ICD-10 Codes that Support Medical Necessity" section- Group 3 and added the following language to the "Indications and Limitations of Coverage" section: "BCR/ABL is indicated in patients with suspected CML with either persistent, unexplained leukocytosis or thrombocytosis." CPT code 81301-Added the following language to the "Indications and Limitations of Coverage" section: "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 Codes 81404-81405 (TP53), Added ICD-10-CM codes C88.8, C92.20, C92.22, C92.90, C92.92, C93.00,	

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
		C93.02, C93.10, C93.12, C93.90, C93.92, C93.Z0, C93.Z2, C94.40, C94.41, C94.42, C94.80, C94.82, C95.00, C95.02, C95.10, C95.12, C95.90, C95.92, C96.9, C96.Z, D45, D47.1, D47.3, D47.4, D47.9, D47.Z9, D61.818, D69.49, D69.6, D69.8, D69.9, D70.8, D70.9, D72.810, D72.818, D72.819, D72.821, D72.828, D72.829, D72.89, D72.9, D75.81, D75.89, D75.9, D77, R16.1, R16.2 to the "ICD-10 Codes that Support Medical Necessity" section-Groups 29. Added "Mesa R, Jamieson C, Bhatia R, et al. Myeloproliferative Neoplasms. NCCN Clinical Practice Guidelines in Oncology. 2017;Version 2.2018." to Sources of Information section. Added sources of information to the Bibliography.	
01/01/2018	R15	Added CPT code 81232 which was inadvertently omitted from CPT/HCPCS Code section- Group 3.	• Typographical Error
01/01/2018	R14	Added the following ICD-10-CM diagnosis codes to the "ICD-10-CM That Supports Medical Necessity section"- Group 1, effective for services rendered on or after January 1, 2018: C25.0, C25.1, C25.2, C25.3, C25.4, C25.7, C25.8, C25.9, C48.1, C50.011, C50.012, C50.019, C50.021, C50.022, C50.029, C50.111, C50.112, C50.119, C50.121, C50.122, C50.129, C50.211, C50.212, C50.219, C50.221, C50.222, C50.229, C50.311, C50.312, C50.319, C50.321, C50.322, C50.329, C50.411, C50.412, C50.419, C50.421, C50.422, C50.429, C50.511, C50.512, C50.519, C50.521, C50.522, C50.529, C50.611, C50.612, C50.619, C50.621, C50.622, C50.629, C50.811, C50.812, C50.819, C50.821, C50.822, C50.829, C50.911, C50.912, C50.919, C50.921, C50.922, C50.929, C56.1, C56.2, C56.9, C57.00, C57.01, C57.02, C61, D05.11, D05.12. Based on a reconsideration request to provide coverage for CPT code 0007M received in March 2017, sources reviewed were added to the Bibliography section. No changes in coverage were made. <i>DATE (01/01/2018): At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; and, therefore not</i>	• Request for Coverage by a Practitioner (Part B)

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
		<i>all the fields included on the LCD are applicable as noted in this policy.</i>	
01/01/2018	R13	Added ICD-10-CM codes Z85.07 and Z85.46 to the "ICD-10-CM that Supports Medical Necessity" section- Group 1, effective for services rendered on or after 01/01/2018. Based on a reconsideration request to provide coverage for CPT code 0007M received in July 2017, sources reviewed were added to the Bibliography section. No changes in coverage were made. <i>DATE (01/01/2018): At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; and, therefore not all the fields included on the LCD are applicable as noted in this policy.</i>	Request for Coverage by a Practitioner (Part B)
01/01/2018	R12	Due to the annual HCPCS update, the following Tier 1 CPT codes were added to CPT/HCPCS section- Group 2: 81105-81112; 81120, 81121, 81175, 81176, 81238; 81247-81249; 81283, 81334, 81335, 81346, 81448, 81521, 81541, 81551. The following Tier 1 CPT codes replaced existing Tier 2 codes and were added to CPT /HCPCS section- Group 3: 81232 replaced 81400-DPYD; 81258, 81259, 81269 replaced 81404-HBA1/HBA2; 81230-81231 replaced 81401-CYP3A4-CYP3A5; 81327 replaced 81401-SEPT9; 81328 replaced 81479-SLCO1B1; 81361-81364 replaced 81404-HBB. ICD-10-CM Diagnosis Code Z85.43 was added to the ICD-10-CM Diagnosis Code section that supports medical necessity- Group 1. Tier 1 CPT code 81520 replaced 0008M and was added to CPT/HCPCS section-Group 1 and to the ICD-10-CM Diagnosis	Revisions Due To CPT/HCPCS Code Changes

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
		Code section that supports medical necessity- Group 26. <i>DATE (01/01/2018): At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; and, therefore not all the fields included on the LCD are applicable as noted in this policy.</i>	
10/01/2017	R11	Due to the annual ICD-10-CM update, the following ICD-10 codes were deleted from the ICD-10 Codes that Support Medical Necessity section: C96.2 was deleted from Group 15 and was replaced by C96.20-C96.22, and C06.29; D47.0 was deleted from Group 15 and was replaced D47.01-D47.02, and D47.09; C96.2 was deleted from Group 22 and was replaced C96.20-C96.22, and C06.29. Due to the annual ICD-10-CM update, the following ICD-10 code description was changed in the ICD-10 Codes that DO NOT Support Medical Necessity section: Z31.5 descriptor was changed from "Encounter for genetic counseling" to "Encounter for procreative genetic counseling". Due to the annual ICD-10-CM update, ICD-10 code, Z36, was deleted from the ICD-10 Codes that DO NOT Support Medical Necessity section and was replaced by Z36.0. Added the following ICD-10-CM code range to the ICD-10 Codes that Support Medical Necessity section for CPT codes 81261-81264, Group 13: C85.10-C85.99, effective for services rendered on or after 4/1/2016. <i>DATE (10/01/2017): At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; and, therefore not all the fields included on the LCD are applicable as noted in this policy.</i>	Revisions Due To ICD-10-CM Code Changes

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
08/01/2017	R10	Added the following screening codes to ICD-10 Codes that DO NOT Support Medical Necessity- Group1: Z13.71, Z13.79, and Z36. <i>DATE (08/01/2017): At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; and, therefore not all the fields included on the LCD are applicable as noted in this policy.</i>	Provider Education/Guidance
06/01/2017	R9	CPT Codes 81162, 81211, 81212, 81213, 81214, 81215, 81216, 81217 Added the following clarifying language to the Indications of Coverage section: " and the results will be used to benefit the individual tested in terms of potential to guide therapeutic decision making." -no change in coverage. CPT Code 81270 Clarified the language in the Indications of Coverage section and deleted "in JAK2 V617F negative individuals" CPT code 81404, and 81405 Added the following clarifying wording in the Indications of Coverage section: 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 code 81404 TP53 (tumor protein 53) (e.g. tumor samples), targeted sequence analysis of 2-5 exons, and CPT code 81405 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 individuals who have Acute Myelogenous Leukemia or Myeloplastic Disease to guide therapeutic	Provider Education/Guidance

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
		decision-making. Added the complete narratives of the following genes to the COVERED MOLECULAR PATHOLOGY PROCEDURES section-: 81404 MEN1 (multiple endocrine neoplasia 1) (eg, multiple endocrine neoplasia type 1, Wermer syndrome), duplication/deletion 81404 TP53 (tumor protein 53) (e.g. tumor samples), targeted sequence analysis of 2-5 exons 81405 TP53 (tumor protein 53) (e.g. Li-Fraumeni syndrome, tumor samples), full gene sequence or targeted sequence analysis of >5 exons 81405 MEN1 (multiple endocrine neoplasia 1) (eg, multiple endocrine neoplasia type 1, Wermer syndrome), full gene sequence Added the complete narrative to the following gene in the NON-COVERED MOLECULAR PATHOLOGY PROCEDURES section- no change in coverage: 81406 RET (ret-proto-oncogene) (eg, Hirschsprung disease), full gene sequence Added CPT codes 81270 (JAK2), and 81219 (CALR) previously Group 6 to Group 14 ICD10CM Codes that support Medical Necessity section. Added CPT codes 81404 and 81405 (RET- MEN Types 2B (81404) and 2A (81405)) to the narrative in Group 24 in the ICD10CM Codes that support Medical Necessity section paragraph and corrected the typographical error by deleting Diagnosis code E83.01. Added the following language to the Indications of Coverage section: CPT codes 81404 TP53 (tumor protein 53) (e.g. tumor samples), targeted sequence analysis of 2-5 exons, and CPT code 81405 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 individuals who have Acute Myelogenous Leukemia or Myelodysplastic Disease to guide therapeutic decision-making.	

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
		Added the following ICD-10-CM codes to Group 29 in the ICD-10-CM Codes that support Medical Necessity section: C92.00, C92.02, C92.30, C92.32, C92.40, C92.42, C92.50, C92.52, C92.60, C92.62, C92.A0, C92.A2, C92.Z0, C92.Z2, C94.00, C94.02, C94.6, D46.0, D46.1, D46.20, D46.21, D46.22, D46.A, D46.B, D46.C, D46.4, D46.Z, D46.9. CPT code 81479 Added the following language to the Indications of Coverage section: RARS (SF3B1 mutation) is considered medically necessary in patients with Myelodysplastic Syndrome to guide therapeutic decision-making.	
02/01/2017	R8	CPT code 81450 was removed from CPT/HCPCS NON-COVERED MOLECULAR PATHOLOGY PROCEDURES -Group 3. Refer to LCD L36926 Genomic Sequence Analysis Panels in the Treatment of Acute Myelogenous Leukemia (AML), effective for services rendered on or after 2/1/2017.	Provider Education/Guidance
01/01/2017	R7	The following revisions are effective for services rendered on or after 1/1/2017: <u>CPT codes 81280, 81281, 81282, 81413, and 81414</u> CPT codes 81280, 81281, and 81282 will be deleted as of 12/31/2016. The genes addressed by CPT codes 81280-81282 are now included in new CPT codes 81413 and 81414. CPT codes 81413 and 81314 also include genes which would have been reported with Tier 2 molecular CPT codes or CPT code 81479 which were considered not medically necessary. Codes 81413 and 81314 will be added to Group 3- NON-COVERED MOLECULAR PATHOLOGY PROCEDURES, effective for services rendered on or after 1/1/2017. No change in coverage. <u>CPT Code 81422</u> Added new CPT code 81422 to Group 3- NON-COVERED MOLECULAR PATHOLOGY PROCEDURES, effective 1/1/2017. For dates of service prior to 12/31/2016, Tier 2 molecular	Revisions Due To CPT/HCPCS Code Changes

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		CPT codes or CPT code 81479 would have been used to report the genes included in this code which were considered not medically necessary. No change in coverage. <u>CPT Code 81439</u> Added new CPT code 81439 to Group 3- NON-COVERED MOLECULAR PATHOLOGY PROCEDURES. For dates of service prior to 12/31/2016, Tier 2 molecular CPT codes or CPT code 81479 would have been used to report the genes included in this code which were considered not medically necessary. No change in coverage. <u>CPT Code 81218</u> Added the following additional ICD-10-CM codes to the ICD-10 Codes that Support Medical Necessity section, Group 5: C92.00, C92.30, C92.02, C92.32, C92.40, C92.42, C92.50, C92.52, C92.A0, C92.A2, C92.Z0, C94.00, C94.02, C92.Z2. Removed ICD-10-CM codes C91.00-C91.02 that had been added previously in error. The ICD-10-CM diagnosis codes now align with the Indications of Coverage for Acute Myelogenous Leukemia (AML). <u>CPT Codes 81245, 81246</u> Added the following additional ICD-10-CM codes to the ICD-10 Codes that Support Medical Necessity section, Group 12: C92.30, C92.32, C94.00, C94.02, C92.Z0, C92.Z2, C92.A0, C92.A2. Removed the following ICD-10-CM codes to the ICD-10 Codes that Support Medical Necessity section, Group 12: C92.01, C92.41, C92.51, C92.61. <u>CPT Codes 81261-81264</u> Corrected the ICD-10 Codes that Support Medical Necessity section, Group 14 to align with the Indications of Coverage by removing the incorrect ranges (C91.00-C91.32, C91.50-C91.62, C91.A0-C93.92) and adding the following specific ICD-10-CM codes to Group 14 : C92.00, C92.02, C92.30, C92.32, C92.40, C92.42, C92.50, C92.52, C92.60, C92.62, C92.A0, C92.A2, C92.Z0, C92.Z2, C94.00, and C94.02. <u>CPT Code 81272</u> Added the following additional ICD-10-CM codes to the ICD-10 Codes that Support Medical Necessity section, Group 16: C92.30, C92.32, C92.Z0, C92.Z2, C92.60, C92.62, C92.A0,	

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		C92.A2, and C94.00, C94.02 <u>CPT Code 81310</u> Added a new ICD-10-CM to CPT code Group 29 to align with the Indications of Coverage for Acute Myelogenous Leukemia (AML). Added the following additional ICD-10-CM codes to the ICD-10 Codes that Support Medical Necessity section, Group 29: C92.00, C92.02, C92.30, C92.32, C92.40, C92.42, C92.50, C92.52, C92.60, C92.62, C92.A0, C92.A2, C92.Z0, C92.Z2, C94.00, and C94.02. The following revisions, not listed in prior Revision History # 6, are effective for services rendered on or after 12/1/2016: <u>CPT Code 81210</u> Added the following additional ICD-10-CM codes to the ICD-10 Codes that Support Medical Necessity section, Group 4: C17.0-C17.9, C18.0-C19, C20, C21.1-C21.8, C78.4, C78.5, Z85.038, Z85.048 <u>CPT 81219</u> Removed CPT code 81219 (CALR) in the ICD-10 Codes that Support Medical Necessity section, Group 15. <u>CPT 81287</u> Added the following ICD-10-CM codes to the ICD-10 Codes that Support Medical Necessity section, Group 18: C71.0 - C71.9 <u>CPT code 81301</u> Added the following ICD-10-CM codes to the ICD-10 Codes that Support Medical Necessity section Group 19: C17.0 - C17.9, C18.0-C18.9, C19, C20, C21.1-C21.8, C33, C34.00-C34.12, C34.2, C34.30-C34.32, C34.80-C34.82, C34.90-C34.92, Z85.038, Z85.048 <u>CPT 81332</u> Added the following ICD-10-CM code to the ICD-10 Codes that Support Medical Necessity section Group 22: E88.01 <u>CPT code 81340, 81341, 81342</u> Added the following ICD-10-CM codes to the ICD-10 Codes that Support Medical Necessity section Group 23: C91.00-	

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		C91.02, C95.90-C95.92, D60.0, D60.1, D60.8, D61.01, D61.09, D61.1-D61.3, D61.89, D61.9	
12/01/2016	R6	Consolidated Molecular Pathology Procedures into three (3) separate CPT/HCPCS section Groups: Group 1- COVERED MOLECULAR PATHOLOGY PROCEDURES, GROUP-2 MOLECULAR PATHOLOGY PROCEDURES THAT REQUIRE INDIVIDUAL REVIEW, and GROUP 3-NON-COVERED MOLECULAR PATHOLOGY PROCEDURES <u>CPT Codes 81162, 81211, 81212, 81213, 81214, 81215, 81216, 81217 (BRCA1 and BRCA2)</u> Removed CPT/HCPCS Codes from Group 2, TIER 1 AND TIER 2 MOLECULAR PATHOLOGY PROCEDURES THAT REQUIRE INDIVIDUAL REVIEW and added to CPT/HCPCS Codes section, GROUP 1- COVERED MOLECULAR PATHOLOGY PROCEDURES. Added ICD-10-CM diagnosis codes Z86.000 and Z85.3 as payable for these CPT codes. <u>CPT code 81170 (ABL1)</u> Revised the Indications of Coverage section by removing the typographical error "chronic lymphoblastic leukemia (CLL)" and replacing with "chronic myeloid leukemia (CML)". Revised the ICD-10 Codes that Support Medical Necessity section, Group 2, by removing the typographical error and replacing ICD-10-CM diagnosis code ranges C91.00-C91.02 and C91.10-C91.12 with ICD-10-CM diagnosis code ranges C92.10-C92.12 and C92.20-C92.22. <u>CPT code 81209 (BLM (Bloom syndrome, RecQ helicase-like))</u> Removed CPT code from TIER 1 NON-COVERED MOLECULAR PATHOLOGY PROCEDURES, Group 3, and added to CPT/HCPCS Codes section, GROUP 1- COVERED MOLECULAR PATHOLOGY PROCEDURES, Group1. Added criteria to the Indications and Limitations of Coverage section. <u>CPT Codes 81220, 81221, 81222, 81223, 81224 (CFTR)</u> Removed CPT codes from CPT/HCPCS Codes section, TIER 1 NON-COVERED MOLECULAR PATHOLOGY PROCEDURES, Group 3, and added to CPT/HCPCS Codes section, GROUP 1- COVERED MOLECULAR PATHOLOGY PROCEDURES. Added	Provider Education/Guidance

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		criteria to Indications and Limitations of Coverage section. <u>CPT code 81272 (KIT)</u> Added 2017 ICD-10-CM diagnosis code range C49.A0-C49.A9 to the ICD-10 Codes that Support Medical Necessity section, Group 16. <u>CPT code 81313 (PCA3)</u> Removed 81313 from CPT/HCPCS Codes section, Group 2, TIER 1 AND TIER 2 MOLECULAR PATHOLOGY PROCEDURES THAT REQUIRE INDIVIDUAL REVIEW and added to CPT/HCPCS Codes section, GROUP 1- COVERED MOLECULAR PATHOLOGY PROCEDURES. Added ICD-10-CM diagnosis code R97.2 to ICD-10 Codes that Support Medical Necessity section, Group 7. <u>CPT Codes 81315, 81316 (PML/RARALPHA, (T(15;17)))</u> Removed CPT codes from CPT/HCPCS Codes section, Group 2, TIER 1 AND TIER 2 MOLECULAR PATHOLOGY PROCEDURES THAT REQUIRE INDIVIDUAL REVIEW, and added to CPT/HCPCS Codes section, GROUP 1-COVERED MOLECULAR PATHOLOGY PROCEDURES. Added ICD-10 Code range C92.40-C92.42 Acute promyelocytic leukemia to ICD-10 Codes that Support Medical Necessity section, Group 8. <u>CPT code 81401 (CBFB-MYH11)</u> Corrected name of gene 81401 CYFB-MYH11 to CBFB-MYH11 in COVERED MOLECULAR PATHOLOGY PROCEDURES section. <u>CPT code 81519 (ONCOLOGY (BREAST), MRNA)</u> Removed CPT code 81519 from Group 7, COVERED MULTIANALYTE ASSAYS with ALGORITHMIC ANALYSES PROCEDURES and added to CPT/HCPCS Codes section, GROUP 1- COVERED MOLECULAR PATHOLOGY PROCEDURES. <u>CPT code 81595 (CARDIOLOGY (HEART TRANSPLANT), MRNA,)</u> Removed CPT code 81595 from Group 7, COVERED MULTIANALYTE ASSAYS with ALGORITHMIC ANALYSES PROCEDURES and added to CPT/HCPCS Codes section, GROUP 1- COVERED MOLECULAR PATHOLOGY PROCEDURES.	

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

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		PROCEDURES section: 81170, 81218, 81225, 81272, 81273, 81276, 81310, 81311, 81314, 81370-81383 Added the following CPT codes to the CPT HCPCS Group 2 TIER 1 AND TIER 2 MOLECULAR PATHOLOGY PROCEDURES THAT REQUIRE INDIVIDUAL REVIEW section: 81162, 81216, 81301 Added the following CPT codes to the CPT HCPCS Group 3 TIER 1 NON-COVERED MOLECULAR PATHOLOGY PROCEDURES section: 81219, 81227, 81355 Added the following CPT codes to the CPT HCPCS Group 5 NON-COVERED GENOMIC SEQUENCING PROCEDURES AND MULTIANALYTE ASSAYS WITH ALGORITHMIC ANALYSES (MAAA) section: 81442, 81490, 81493, 81500-81507, 81525, 81535, 81538, 81540, 81595 Added CPT code and ICD-10-CM diagnosis code groupings in ICD-10-CM Diagnosis Codes that Support Medical Necessity section for the following CPT codes: 81170, 81218, 81245-81246, 81272-81273, 81275-81276, 81311, 81314, 81401, 81404, 81405, 81406 Added the following CPT code ranges to the CPT HCPCS Group 6 NON-COVERED ADMINISTRATIVE MULTIANALYTE ASSAYS WITH ALGORITHMIC ANALYSES (MAAA) section: 0001M-0004M, 0006M-0010M Added the following language to bullet number 6 in the Indications of Coverage section: "Exceptions include clinical scenarios whereby repeat testing of somatically-acquired mutations (for example, pre- and post- therapy) may be required to inform appropriate therapeutic decision-making."	
01/01/2016	R2	Based on the CPT/HCPCS annual update, the descriptions for the following codes have been changed: 81210, 81275, 81355, 81402.	Revisions Due To CPT/HCPCS Code Changes
10/01/2015	R1	LCD updated to reflect administrative changes.	Provider

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Associated Documents

Attachments

N/A

Related Local Coverage Documents

Article(s)

A56199 - Billing and Coding: Molecular Pathology Procedures

A55982 - Response to Comments: Molecular Pathology Procedures

Related National Coverage Documents

N/A

Public Version(s)

Updated on 05/28/2020 with effective dates 07/01/2020 - N/A

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