Local Coverage Determination (LCD): Flow Cytometry (L34651)

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Contractor Information

Contractor Name	Contract Type	Contract Number	Jurisdiction	State(s)
Wisconsin Physicians Service Insurance Corporation	MAC - Part A	05101 - MAC A	J - 05	Iowa
Wisconsin Physicians Service Insurance Corporation	MAC - Part B	05102 - MAC B	J - 05	Iowa
Wisconsin Physicians Service Insurance Corporation	MAC - Part A	05201 - MAC A	J - 05	Kansas
Wisconsin Physicians Service Insurance Corporation	MAC - Part B	05202 - MAC B	J - 05	Kansas
Wisconsin Physicians Service Insurance Corporation	MAC - Part A	05301 - MAC A	J - 05	Missouri - Entire State
Wisconsin Physicians Service Insurance Corporation	MAC - Part B	05302 - MAC B	J - 05	Missouri - Entire State
Wisconsin Physicians Service Insurance Corporation	MAC - Part A	05401 - MAC A	J - 05	Nebraska
Wisconsin Physicians Service Insurance Corporation	MAC - Part B	05402 - MAC B	J - 05	Nebraska
Wisconsin Physicians Service Insurance Corporation	MAC - Part A	05901 - MAC A	J - 05	Alaska Alabama Arkansas Arizona Connecticut Florida Georgia Iowa Idaho Illinois Indiana Kansas Kentucky Louisiana Massachusetts Maine Michigan Minnesota Missouri - Entire State Mississippi Montana North Carolina North Dakota Nebraska New Hampshire New Jersey Ohio Oregon Rhode Island South Carolina South Dakota Tennessee Utah

Contractor Name	Contract Type	Contract Number	Jurisdiction	State(s)
				Virginia Virgin Islands Vermont Washington Wisconsin West Virginia Wyoming
Wisconsin Physicians Service Insurance Corporation	MAC - Part A	08101 - MAC A	J - 08	Indiana
Wisconsin Physicians Service Insurance Corporation	MAC - Part B	08102 - MAC B	J - 08	Indiana
Wisconsin Physicians Service Insurance Corporation	MAC - Part A	08201 - MAC A	J - 08	Michigan
Wisconsin Physicians Service Insurance Corporation	MAC - Part B	08202 - MAC B	J - 08	Michigan

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LCD Information

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Title XVIII of the Social Security Act section 1833 (e). This section prohibits Medicare payment for any claim which lacks the necessary information to process the claim.

Title XVIII of the Social Security Act section 1862 (a) (1) (A). This section excludes coverage and payment of those items or services that are not considered to be *medically 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 section 1862 (a) (1) (D). This section states that no Medicare payment may be made under part A or part B for any expenses incurred for items or services that are investigational or experimental.

Title XVIII of the Social Security Act section 1862 (a)(7). This section excludes routine physical examinations and services.

42 CFR, Section 410.32 (b) *Diagnostic x-ray and other diagnostic tests. (1) Basic rule. .. all diagnostic x-ray and other diagnostic tests covered under section 1861(s)(3) of the Act and payable under the physician fee schedule must be furnished under the appropriate level of supervision by a physician as defined in section 1861® of the Act. Services furnished without the required level of supervision are not reasonable and necessary. (see 42 CFR 411.15(k)(1)).*

CMS Pub 100-02 *Medicare Coverage Policy Manual*, Chapter 6 – Hospital Services Covered Under Part B, Section 20.4 – Outpatient Diagnostic Services.

CMS Pub 100-04 *Medicare Claims Processing Manual*, Chapter 25 - Completing and Processing the form CMS – 1450 Data Set, Section 75 – General Instructions for Completion of Form CMS – 1450 for Billing, 75.5 – Form Locators 43-65, 75.5- Form Locators 66-81.

CMS Pub 100-08 *Medicare Program Integrity Manual*, Chapter 3 – Verifying Potential Errors and Taking Corrective Actions, Sections
3.4.1.3 – Diagnostic Code Requirements and
3.6.2.3 – Limitation of Liability Determinations.
Chapter 13 – Local Coverage Determinations, Sections
13.7.1 – Evidence Supporting LCDs and
13.11- LCD Reconsideration Process.

CMS Pub 100-09 *Medicare Contractor Beneficiary and Provider Communication Manual*, Chapter 5 – Correct Coding Initiative.

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

Overview:
Flow Cytometry (FCM) is a highly complex cell analysis process performed by allowing cells in liquid suspension to pass through a laser-produced beam of light for the actual analysis of the cell. Specimens are usually treated with reagents that are chosen to amplify certain signals, such as antigens on a cell surface or within the cytoplasm or nucleus, or DNA content within a cell. The light activates fluorescent molecules, resulting in light scatter, which forms a pattern that can be analyzed for cell characteristics such as cell size, internal structure, antigens, DNA, ploidy (the number of single sets of chromosomes in a cell or organism), and cell cycle analysis of single cells in a

moving fluid stream. FCM can be used to analyze blood, body fluids, cerebrospinal fluid, bone marrow, lymph node, tonsil, spleen, and other solid organs. This information may help to determine prognosis, aid in the analysis of effusions, urine, or other fluids in which cancer cells may be few or mixed with benign cells, detect metastases in lymph nodes or bone marrow, and/or to supplement fine needle aspiration. Clinical analysis and interpretations are performed by an experienced physician, usually a pathologist or hematopathologist.

The flow cytometer is made up of three main systems: fluidics, optics and electronics. The fluidic system transports particles in a stream to the laser beam. The optics system consists of lasers to illuminate the particles in the sample stream and optical filters to direct the resulting light signals to the appropriate detectors. The electronics system converts the detected light signals into electronic signals that can be processed by the computer. Some flow cytometers have a sorting feature which allows the electronic system to initiate sorting decisions to charge and deflect particles.

Immunophenotyping
The cells of the immune system bear on their surfaces and within their cytoplasm or nucleus hundreds of molecules specific for their particular developmental stage and functional state. There have been more than 260 types of molecules identified on the surface of human leukocytes but only around 30 of these are associated with a known structure or function.

The process of measuring the types of antigens expressed on and within a cell by flow cytometry is referred to as immunophenotyping. To detect these antigens, antigen-specific monoclonal antibodies are used which have been labeled with a fluorescent dye or fluorochrome. After washing away any unbound antibody, the cells are analyzed by flow cytometry which categorizes them by size, granularity and fluorochrome intensity. An international standard nomenclature is used to categorize most antibodies according to the antigens they detect. Each category is called a cluster of differentiation (CD) and is numbered. A few clinically useful antibodies have not yet been "clustered" and are referred to by names derived from site of origin or nomenclature used in other classification systems (e.g. histocompatibility and immunoglobulin antigens).

DNA content (ploidy) and cell proliferative activity (S-phase fraction or % S-phase)
Malignant cells sometimes show abnormalities in total chromosome number and the frequency of these abnormalities generally increases with progression to higher-grade tumors. Flow cytometric methods can be used to measure nuclear deoxyribonucleic acid (DNA) content (ploidy) as a prognostic indicator of solid tumors. Fluorescent dyes are used to stain nucleic acids. DNA diploid tumors are those where a single peak containing an amount of DNA similar to normal cells is generated by flow cytometry. DNA aneuploid tumors have additional peaks on the DNA histogram which may represent cells containing more or less nucleic acid found in 46 normal chromosomes. Aneuploidy tumors have a chromosome number that is not an exact multiple of the normal diploid number, with either fewer or more than the normal number of chromosomes in the cell. In humans, an aneuploidy cell would be considered abnormal. A triploid cell (having three times the haploid number of chromosomes in the cell nucleus) and would be an example of aneuploidy in humans.

A more quantitative method of expression is the DNA index (DI), which is the ratio of the mean tumor sample G0/G1 DNA content divided by the mean G0/G1 DNA content of normal diploid reference cells. The greater the deviation of the DI from 1, the more "aneuploid" the tumor.

The assessment of % S-phase or the S phase fraction (SPF) measures the percentage or proportion of cells preparing for mitosis by their active doubling of DNA. Tumor cells tend to replicate more readily than normal cells therefore increased SPF activity can raise the question of malignancy. Frequently a high SPF will correlate positively with poor differentiation, increasing tumor size and degree of aggressiveness.

The specimen analysis is dependent on the diagnosis of the patient

Indications

1. **Leukemia or Lymphoma**

Leukemias and lymphomas may be analyzed from any solid tissue, blood, bone marrow or other fluids (e.g. cerebrospinal fluid, bronchoalveolar lavage, pleural and peritoneal fluids). Flow cytometry may be performed on peripheral blood and fine needle aspirate material, thus avoiding more invasive procedures for diagnosis. The presence or absence of antigens is determined using an appropriate antibody panel for differential diagnosis. This process may be necessary at the initial diagnostic phase, for evaluation of separate hematologic malignancies, or when tumor is present in several anatomic sites. It may also be necessary where there is abnormal tissue, bone marrow or blood histology, where results are suspicious for lymphoma or leukemia, and where the physician must distinguish reactive from neoplastic conditions; and morphologic exam is not sufficiently sensitive to resolve the diagnosis (e.g. minimal disease, either de novo or residual, after therapy).

Once a specimen is received the pathologist assesses the clinical history, reviews the morphology of the specimen (i.e. blood smear, bone marrow smear, and lymph node) and determines if the lesion is amenable to analysis by flow cytometry. This is a key step, as the initial clinical and or morphologic examination of the specimen may distinguish among potential "mature" lymphoproliferative disorders, acute leukemias and other conditions that may or may not be appropriate for cytometric evaluation.

Where flow cytometry has previously established a diagnosis, and where the neoplastic cells have a characteristic phenotype, it may be unnecessary to extensively re-phenotype the lesion; instead, a limited analysis may be used that allows the pathologist to definitively identify the abnormal cell population while referring back to the original phenotype. However, this approach may not be appropriate for complex fluid samples (e.g. marrow) or for acute leukemia, where changes in antigen profiles at relapse or post chemotherapy are not uncommon.

2. **Leukemia**

Flow cytometric analysis of blood and marrow mononuclear cells can generally differentiate between polyclonal and monoclonal (monotypic) B- cell lymphoproliferative disorders or lymphoid neoplasms. It can also define certain atypical gains and losses of T- cell related antigens that are associated with clonal T-cell lymphoproliferations.

At a minimum, flow cytometric analysis for mature B- cell or T-cell lymphoproliferations should evaluate leukemic cells for expression of multiple pan B-cell or T-cell lymphoid differentiation antigens, intrinsic (non-Fc bound) surface immunoglobulins, light chains (kappa and lambda), and additional leukocyte antigens, that help to distinguish between the various T- or B- cell leukemias. Additional antigens, such as CD38 and ZAP70, may provide prognostic information.

In the situation of plasma cell neoplasms (e.g. myeloma, MGUS), a smaller panel directed at both cell surface and cytoplasmic immunoglobulin light chains would be appropriate. The acute leukemic panel is designed to distinguish whether leukemic blasts are of myeloid or lymphoid origin and if the latter, whether they are T- or B- cell lineage. For the B- cell lineage certain differentiation antigens are prognostically useful.

The acute leukemia panel may also be necessary for the detection of minimal residual disease in post-therapy bone marrow samples from leukemic patients. Because of the need to define the presence of a given atypical profile, both the initial and post therapy panels require additional antigens to fully characterize the neoplastic cells.

3. **Acute Myeloid or Lymphoid Leukemia**

The diagnosis and management of acute leukemia depend on the detection, identification and characterization of leukemic cells. Each acute leukemia subgroup has heterogeneous biologic characteristics, many of which are associated with a different response to therapy. As part of a routine diagnostic workup, most suspected acute leukemia cases undergo initial multiparameter immunophenotypic analysis, combined with morphology, cytochemistry, cytogenetics, and molecular biology. A standard acute leukemia flow cytometry panel is designed to determine whether leukemic blasts are of myeloid or lymphoid origin, and then to further classify the neoplastic cells (myeloid blasts, B lymphoblasts, abnormal promyelocytes, monoblasts, etc.). When the routine panel is insufficient to characterize the leukemic cells, additional antibodies including erythroid markers (CD71 and glycophorin A), megakaryocytic markers (CD41, CD61) or cytoplasmic markers may be indicated.

4. **Chronic Lymphocytic Leukemia (CLL) & Other Chronic Lymphoproliferative Diseases (CLPD)**

The history, physical exam (lymphadenopathy, splenomegaly and/or hepatomegaly) laboratory findings (lymphocytosis, granulocytopenia, anemia, thrombocytopenia), and lymphocyte morphology are suggestive of CLL. The diagnosis is established by paradoxical co-expression of CD5 on peripheral lymphocytes that express B cell markers (CD19, CD20, CD21 and CD23) with Kappa or lambda immunoglobulin light chain restriction. Additional markers such as CD38 and ZAP70 may provide important prognostic information. Flow cytometry can distinguish CLL, the peripheral counterpart of small lymphocytic lymphoma, often diagnosed in lymph node biopsies, from other indolent lymphocytic malignancies including prolymphocytic leukemia, Waldenstrom's macroglobulinemia, leukemic phase of lymphomas, hairy cell leukemia, T-cell CLL, adult T-cell leukemia, large granulocytic leukemia and cutaneous T-cell lymphoma and natural killer (NK) disorders including KIR (Killer cell Immunoglobulin-like receptors) expression.

5. **Myelodysplasia (MDS)**

Hematological (blood related) medical conditions with ineffective production of the myeloid class of blood cells. The blood production is disorderly and ineffective. Those with MDS can develop severe anemia and require blood transfusions. If the disease worsens, cytopenias can progress to bone marrow failure.

Flow cytometric immunophenotyping is also useful in immunophenotyping MDS, because it allows for the detection of an accurate percentage of myeloblasts; microblasts are characteristic of MDS and often difficult to morphologically differentiate from lymphocytes. Also of interest, the use of 4-color flow cytometry has allowed for the identification of abnormal myeloid populations in more than 90% of non–chronic myeloid leukemia myeloproliferative disorders (MPDs) and MDSs with a clonal cytogenetic abnormality, supporting the use of FCI in the diagnosis of these disorders. Flow cytometric immunophenotyping may also allow for the detection of an accurate percentage of monocytic cells, by analyzing CD14 and CD64, in establishing a diagnosis of chronic myelomonocytic leukemia (CMML). In addition, the morphologically mature monocytes of CMML may reveal abnormalities by FCI (partial loss of CD13, CD14, and CD15 and expression of CD56) that are not observed in normal monocytes. These abnormalities may indicate clues to a correct classification of CMML in these cases. (Dunphy)

6. **Lymphoma**

In the current World Health Organization (WHO) classification, all non-Hodgkin lymphomas (NHLs) are distinct clinicopathologic entities defined by their clinical features, morpholology, and immunophenotype plus, where appropriate, their genetic abnormalities. Immunophenotyping by flow cytometry allows multiparameter evaluation of single cells and the ability to work on very small samples.

An adequate biopsy is key to diagnosis and staging of lymphomas, and is often diagnostic in and of itself. Flow cytometry is usually a secondary test. However, some lymphoid proliferations can be morphologically confused with lymphoma. Further the use of fine needle aspirate biopsy (FNA) results in the loss of the biopsy architecture, a key feature in distinguishing benign from neoplastic lymphoproliferations. Lastly, the biopsy and FNA are not always able to distinguish clinically significant forms of lymphoma (e.g. mantle cell NHL). All of these situations are indications for flow cytometry and assist with the diagnosis, the prognosis, and the treatment of patients with lymphoma.

The panels of antibodies to leukocyte antigens are designed to identify and characterize lymphoproliferative disorders, which are usually comprised of mature B, T or plasma cells. Flow cytometric testing on blood or bone marrow for anaplastic large cell lymphoma, lymphomatoid granulomatosis (LYG), thymic B cell lymphoma, diffuse large B-cell lymphoma, plasma cell neoplasms or large cell lymphoma must be cautiously interpreted because of false negative results due to tumor cell loss in this disease population.

For B cell malignancies, demonstration of the presence of monoclonal population by restricted kappa or lambda, immunoglobulin light chain expression is useful, particularly when augmented by other differentiation antigens. These combined with a pan B antigen can not only help support the diagnosis of neoplasia, but significantly assist in defining the specific type of B cell lymphoma.

For T cell proliferations, clonality can usually be assessed using two complementary approaches. The first and newest is to use well-defined panels of 20 antibodies to TCR V beta genes. The other, more indirect method looks for atypical absence of well-defined pan T antigens and /or atypical intensities of pan T antigens may serve as reasonably specific markers of clonality. Lastly, atypical coexpression of certain antigens is helpful in defining certain subsets of T cell lymphomas. To render a formal diagnosis of T cell lymphoma, such flow data needs to be correlated with morphology and in some instances TCR gene clonality, HTLV serologic and or cytogenetic studies.

In the situation of plasma cell neoplasm (e.g. plasmacytoma, multiple myeloma) a smaller panel directed at both cell surface immunoglobulins light chains and cytoplasmic immunoglobulin light chains would be appropriate. Plasma cells develop from B lymphocytes (B-cells), a type of white blood cell that is made in the bone marrow. Plasma cell neoplasms are diseases in which abnormal plasma cells or myeloma cells from tumors in the bones or soft tissues of the body. Plasma cell neoplasms can be benign or malignant.

Flow cytometry can help define Natural Killer (NK) cell lineage in rare neoplastic NK proliferations. NK cells, belonging to the group of innate lymphoid cells, are defined as large granular lymphocytes (LGL) and constitute the third kind of cells differentiated from the common lymphoid progenitor generating B and T lymphocytes. NK cells are known to differentiate and mature in the bone marrow, lymph node, spleen, tonsils, and thymus where they enter into the circulation. Expression of the KIR family of NK-cell receptors has been used as a surrogate marker for clonality in NK cell disorders. For example, in chronic lymphoproliferative disorders of NK cells, expression of the KIR family is abnormal—either restricted isoform expression or a complete lack of detectable expression. Evaluation of KIR expression by flow cytometry can thus be used as evidence of a chronic NK-cell lymphoproliferative disorder versus a reactive NK-cell proliferation.

However, there are no immunophenotypic markers for clonality. In these instances, careful correlation with clinical course or molecular or cytogenetic testing may assist. The panel would be performed in stages and may include up to 20 antibodies for lymphomas. A standard lymphoma panel is designed to identify abnormal populations of B cells, T cells and/or NK cells. A standard lymphoma panel might include a combination of markers from the following categories: T cells, B cells, Kappa and lambda surface immunoglobulins light chains, and plasma cells. The immunophenotypes of lymphomas are widely known and flow cytometry allows appropriate classification of most cases. However, atypical patterns occur and pose significant diagnostic difficulties where aberrant antigen expression patterns must be reconciled with morphology. Additional markers may be required to characterize the abnormal population of cells including markers of immature cells (HLA-DR), B cells and myeloid cells.

7. **Histiocytic and Mast Cells**

In the premier diagnostic text for hematopathology, *World Health Organization Classification of Tumours of Haematopoetic and Lymphoid Tissues*, the demonstration of an aberrant mast cell phenotype is listed as independent criteria for the diagnosis of mast cell disease. This diagnostic criterion is based upon immunohistochemistry or flow cytometry. However, within the literature, the advantage of flow cytometric analysis in the detection and evaluation of mast cells has been touted due to the high sensitivity and objectivity that multiparametric analysis of a high number of cells can afford. Flow cytometry in mast cell evaluation is also of utility because it can aid in the identification of coexisting hematological malignancies, such as lymphoma, acute myeloid leukemia, myelodysplasia, and chronic myeloproliferative disorders that can accompany systemic mastocytosis in roughly one third of cases. Mast cell neoplasms are uncommon disorders. They are part of the immune system.

8. **Lymphocytosis (symptomatic)**

Flow cytometry may be indicated when signs and symptoms may suggest the presence of hematolymphoid neoplasm, and where flow cytometry is a useful tool in establishing the primary diagnosis. Flow cytometry is indicated where the up front utilization have a reasonable likelihood of diagnostic yield. These diagnoses include absolute lymphocytosis, lymphadenopathy and splenomegaly. This does not mean that it is necessary to randomly check lymphoproliferative disorders in peripheral blood specimens. Multiple flow cytometric strategies are used to evaluate hematolymphoid populations, including identification of neoplastic populations with aberrant immunophenotypes, abnormal maturation patterns, monotypic kappa/lambda light chain expression, restricted V-beta expression, and abnormal light scatter properties. (Calvo)

9. **Enlargement of Lymph Nodes**

Because of its increased specificity and in some cases increased sensitivity, flow cytometry has emerged as a primary diagnostic modality in the diagnosis of non-Hodgkin lymphoma and lymphoproliferative neoplasms and is no longer considered an ancillary tool. There is significant consensus to show the effectiveness of flow cytometry in diagnosing hematolymphoid neoplasms in the absence of obvious morphologic abnormalities. Delaying the ordering of flow cytometry until there is a review of the histologic sections because flow cytometry requires fresh tissue and even within 24 hours, the viability of neoplastic cells is reduced. Cytomorphologic examination and multiparametric flow cytometry (C-FCM) has proven to be an indispensable diagnostic and classification tool for chronic lymphoproliferative disorders with peripheral blood and bone marrow involvement. But C-FCM is valid not only for chronic lymphoproliferative disorders but also for other hematologic malignancies, including acute myeloid leukemia and lymphoblastic leukemia, in which histopathologic study is of little value. Flow cytometry is proved to be a very efficient diagnostic technique and properly classifies low-grade B-cell non-Hodgkin lymphomas. (Colorado)

10. **Transplants**

a. **Organ Transplants**

Postoperative monitoring of organ transplants may be necessary to determine early rejection, immunosuppressive therapy toxicity, or differentiation of infection from allograft rejection.

The cell surface marker examined is CD3. This may require repeated analysis when symptoms are expressed for the above conditions by the transplant patient. Flow cytometry is also used in the evaluation for the presence of a post-transplant lymphoproliferative disorder. Since even low levels of antibodies have been associated with early rejection episodes and graft loss, antibody detection by flow cytometry has become a routine technique for the study of donor and recipient compatibility. Flow cytometry is a valuable tool to monitor allograft recipients both pre and post transplantation, with the detection and characterization of HLA-specific alloantibody being the principal application in organ transplantation. With the use of flow cytometry antibody detection, donors expressing any of these antigens would be avoided, increasing the likelihood that, when a donor is cross matched with the particular candidate recipient, the final result will be negative. Detection of antidonor antibodies can confirm a suspected diagnosis of rejection and the need for antirejection therapy, indicate bone marrow toxicity during immunosuppressive therapies, and help in the differentiation of infections from transplant rejection. (Kirmizis)

b. **Stem Cell Transplants**

To measure stem cell counts (e.g. CD34, CD45) in patients undergoing autologous transplantation, flow cytometry offers the ability to examine rapidly thousands of cells stained with monoclonal antibodies conjugated to fluorescent dyes. Each cell is individually assessed for a variety of characteristics such as size and biochemical and/or antigenic composition. High precision and sensitivity, combined with the large numbers of cells that can be examined permits resolution of even very minor subpopulations from complex mixtures with high levels of statistical validity. The capacity to physically separate these subpopulations by flow sorting allows further functional, morphological and molecular correlations to be determined. (Preffer)

11. **Primary Immunodeficiencies (PIDS)**

Primary immunodeficiencies (e.g., Lymphocyte disorders, Phagocyte disorders, Monocyte/macrophage disorders, Chronic Granulomatous Disease) are immune disorders that are present at birth. These conditions are quite rare. Diagnosis typically occurs at an early age due to recurrent infections with frequent treatment failures. Affected individuals are prone to repeated infections, allergies, autoimmune disorders, and malignancies. In 2009, more than 120 inherited immunodeficiency disorders were currently recognized and placed in eight classes of PIDs. Initial evaluation for suspected primary immunodeficiencies includes physical exam, laboratory evaluation (e.g., CBC which includes platelet count and WBC with differential, ESR), and may include skin testing. Flow cytometry is indicated for diagnostic purposes in the presence of established disease or when abnormal results are found in the initial evaluation. The immunophenotypic evaluation of selected PIDs provides diagnostic clues as well as information useful to classify patients and predict clinical outcome. Functional flow cytometry can now help to clarify possible sites of genetic defects associated with specific PIDs. (Oliveira)

12. **Paroxysmal Nocturnal Hemoglobinuria (PNH)**

Paroxysmal nocturnal hemoglobinuria is a disease in which blood cells are unusually sensitive to lysis by complement. This condition is caused by a genetic mutation that results in the absence of over a dozen surface antigens on red and white blood cells. It can be diagnosed very efficiently by assessing both the red and white blood cells by flow cytometry for the absence of these antigens. In general staining both the red and white blood cells with fluorescent inactivated aureolysin (FLAER) and/or with antibodies to some of the missing GPI-anchored-antigens (such as CD59, CD14 and CD55) will allow for a very rapid and accurate diagnosis. PNH is a rare clonal hematopoietic disorder of stem cells.

13. **HIV Infection**

The clinical status of an HIV-infected patient can be monitored by the analysis of the surface antigens CD4 (a T-cell receptor for HIV) and CD8. This information can contribute to a staging as well as medical management for that individual (e.g., the need for drug therapy or prophylaxis). Monitoring would be considered appropriate no greater in frequency than once every 3 months. When a patient is stable, especially during the long period of clinical latency, assays would be appropriate at a frequency less often. When the patient has an acute problem and/or therapy change, it may be necessary to perform the test at an increased frequency. Flow cytometry provides important clinical information that helps predict disease outcome and guide treatment decisions. The strongest predictors of disease progression and need for further therapeutic intervention are CD4+T-cell count and viral load. These predictors do not capture an individual's risk for disease progression.

Note: In addition to flow cytometry, other tests are used to evaluate and follow this disease such as: T cell total count and or T cell; absolute CD4 and CD8 count including ratio.

On initial evaluation, additional T cell markers may be indicated. Flow Cytometry has helped define many new T-cell subsets. HIV infection causes significant changes in number of CD4 and CD8 positive lymphocytes, CD4 count falls roughly 30 % while CD8 count increases within 6 months after seroconversion, causing a decrease in the CD4/CD8 ratio. Following HIV infection diagnosis, flow cytometry should include enumeration of mature T-cells (CD3), helper T cells (CD4), and suppressor T cells (CD8) to ensure all major T cell subsets are accounted for (the sum of helper CD4 and suppressor CD8 cells is roughly close to the total number of CD3 positive T cells). This ensures that the absolute CD4 is not artificially decreased due to sample degradation or other artifact. A WBC count with differential also needs to be performed to calculate the absolute CD4 count (absolute lymphocyte count times CD4%). (CDC)

14. **Drug Monitoring**

Drugs that react against specific monoclonal antibodies are being developed to treat certain diseases that impact the immune system. Conventional therapeutic drug monitoring based on measuring immunosuppressive drug concentrations in blood is important in the clinical management of immunosuppressive therapy in transplantation medicine. Since rejection or infection occurs at irregular drug concentrations immunosuppressive drug therapy is often empiric and prophylactic in nature. In addition, blood immunosuppressant levels are only indirect predictors of the pharmacologic effects on immune cells, because the genetic heterogeneity the immune systems of transplant recipients are not equally sensitive to drug effects. Therefore, therapeutic drug monitoring requires the application of reliable and effective methods to study the pharmacodynamics variability by direct measurements of drug effects on immune cell functions. Flow cytometry offers a multiplicity of quantitative analysis possibilities, from detection of phosphorylated molecules up to complex multicolor analysis of whole blood samples. A large spectrum of flow cytometry-based applications for pharmacodynamic monitoring is available and allows detection and analysis of diverse function of T cells and dendritic cell subsets. By combining several assays, it is possible to generate a broad picture of the immune status of every single transplanted recipient. Furthermore, it is even possible to differentiate between synergistic and antagonistic pharmacodynamic effects of immunosuppressive drug combination therapy in vitro and to predict the pharmacodynamic drug effects in transplanted recipients. Such a pharmacodynamic drug monitoring may offer the opportunity to complete conventional therapeutic drug monitoring and, therefore, to tailor immunosuppressive therapy more individually. (Dieterlien) Through phosphor-specific flow cytometry the efficacy of immunosuppressive medication can be assessed, novel targets identified, and differences in drug sensitivity between cells and patients can be clarified. By analyzing the activity of intracellular signaling pathways in large patient populations, patient-specific differences in immune reactivity, drug susceptibility, and drug related side effects will be able to be determined. (Baan)

15. **Hereditary Persistence of Fetal Hemoglobin (HPFH)**

Hereditary persistence of fetal hemoglobin (HPFH) is a group of disorders in which hemoglobin F (the dominant hemoglobin in the developing fetus) persists into adult life. By itself this disorder is usually clinically benign. However, HPFH is sometimes inherited together with thalassemias and other hemoglobinopathies such as hemoglobin S (sickle cell trait). In these latter conditions, the presence of high levels of hemoglobin F modifies the clinical severity of the thalassemia or the hemoglobin S disorder. Complicating matters though is the observation that some patients with sickle cell disease have an increase in hemoglobin F levels that is not due to HPFH. These patients can have a relatively severe clinical course. Thus, it is critical to separate patients with homozygous hemoglobin S and physiologic increases in hemoglobin F levels from patients with heterozygous hemoglobin S and HPFH. Flow cytometry is a very effective way to distinguish between these two conditions. In most cases of HPFH, every red blood cell has about the same amount of hemoglobin F (called a "homocellular distribution") whereas in physiologic increases in hemoglobin F, the concentration of hemoglobin F varies from one red blood cell to the next (called a "heterocellular distribution"). Using antibodies to hemoglobin F, flow cytometry can readily distinguish a homocellular from a heterocellular hemoglobin F distribution and therefore distinguish HPFH from physiologic increases in hemoglobin F. The test would be indicated in anyone with an unexplained increase in hemoglobin F.

16. **Red Blood Cell Disorders (Hereditary Spherocytosis)**

A recently developed fluorescent dye method has great utility in the diagnosis of hereditary spherocytosis. In the past, the diagnosis of hereditary spherocytosis was based on recognizing spherocytes on the peripheral blood smears and by performing a test called the osmotic fragility test. The osmotic fragility test is sensitive and picks up most patients with hereditary spherocytosis, but it lacks specificity, because patients with other causes of hemolytic anemia can have an abnormal osmotic fragility result. Using flow cytometry with a fluorescent dye (eosin-5-maleimide) one can distinguish hereditary spherocytosis (the red blood cells have weaker staining with the dye) from other causes of spherocytosis (the red blood cells have normal binding to the dye). When coupled with the traditional tests (osmotic fragility and review of blood cell morphology), this has proven to be a very useful test. Flow cytometry for hereditary spherocytosis would be indicated in patients who have Coombs' negative hemolytic anemia.

17. **White Blood Cell Disorders (HLA-B27)**

An increased incidence of the HLA-B27 antigen has been reported in patients with ankylosing spondylitis, Reiter's syndrome, anterior uveitis, psoriatic arthritis, and inflammatory bowel disease. As a result, tests for the HLA-B27 antigen are a valuable adjunct in the diagnosis of these diseases. Traditionally, it has been the lymphocytotoxicity assay that was used to determine HLA status. The development of monoclonal antibodies to HLA antigens has rendered flow cytometry an alternative procedure which is economical and relatively simple. HLA-B27 typing by flow cytometry is performed as a lysed whole blood technique using a single color, directly conjugated antibody and gated peripheral blood lymphocytes as the marker population.

18. **Platelets Cell Disorders**

The use of flow cytometry in the quantitative and qualitative analysis of platelets is becoming more evident and will likely be part of the work-up of coagulation defects of primary and secondary hemostasis in the near future. For example, flow cytometry has been utilized for analysis of platelets in quantitative and qualitative disorders such as Glanzmann Thrombasthenia (GT) and Bernard-Soulier Disease (B-S).

GT is a rare inherited or acquired platelet disorder that derives from a defective GPIIA/GPIIIb receptor. Normally, the GIIA/GPIIIb receptor is involved in platelet cross linking by serving as a receptor for fibrin, thereby creating the initial platelet plug at the site of endothelial injury. Absence of this receptor results in increased susceptibility to bleeding. As demonstrated by Jennings, platelets with decreased expression or absence of the GPIIa/GPIIIb receptor can be easily distinguished in patients with GT by flow cytometry. Demonstration of decreased surface expression provides evidence as to the presence of hereditary GT. Acquired GT is more of an autoimmune phenomenon with the presence of GPIIb/GPIIIa blocking antibodies. Giannini et al, recently reported the ability to use flow cytometry as a rapid test to determine both the functional effect and identity of the molecular targets of these antibodies.

Bernard-Soulier (B-S) Disease is another rare inherited disorder that prevents the initial binding of platelets at the site of endothelial injury by absence of or presence of abnormal surface GPIa/V/IX receptor. Abnormalities of this receptor thereby prevent attachment of platelets to subendothelial or free von Willebrand's factor with subsequent tendency to bleed. Flow cytometry can be used to measures antibodies directed at specific loci of the GPIa/V/IX receptor which include GPIb (CD42b), GPIX (CD42a), and GPV (CD42d). Another characteristic of B-S Disease that can be utilized in the initial evaluation of the flow cytometric data is the size of platelets. In B-S disease platelets are generally larger than normal and may demonstrate an increase spectrum of size that can be distinguished from fragmented RBCs and debris by specific binding of antibodies directed to the GPIb/IX/V receptor, as previously mentioned.

19. **Plasma Cell Disorders**

Plasma cell disorders are a condition in which there is an increase population of plasma cells, including malignant and nonmalignant disorders. Plasma Cell Disorders are identified through a combination of clinical, laboratory studies (urine or serum gamma globulins), morphologic, and radiologic findings. Flow cytometry immunophenotyping is useful to identify abnormal plasma cells, and the distinction between lymphoid and plasma cell neoplasms, and between reactive plasma cells and neoplastic cells. Flow cytometry is also help in the differential diagnosis of myeloma and lymphoma. Flow cytometry is particularly useful in those patients with low tumor burden, because it defines with precision the percentage of clonal plasma cells infiltrating the bone marrow. Moreover, in patients without paraproteins, flow cytometry can distinguish whether the plasma cells in the bone marrow can be polyclonal (= reactive plasmacytosis) instead of monoclonal (= MM or MGUS). For clonal PC disorders, MFC (multiparameter flow cytometry) is of clear and established clinical relevance in: (1) the differential diagnosis between MM and other PC-related disorders; (2) the identification of high-risk MGUS and smoldering MM; (3) minimal residual disease investigation after therapy; additionally, it may also be useful for (4) the definition of prognosis-associated antigenic profiles; and (5) the identification of new therapeutic targets. MM is Multiple Myeloma and MGUS is monoclonal gammopathy of undetermined significance. Other types of plasma cell disorders include M- component, Smoldering multiple myeloma, Plasma cell leukemia, Waldenstrom macroglobulinemia, HDT (high dose melphalan)/ASCT (autologous stem cell), and Immune paresis. (Paiva)

20. **Chronic Myeloproliferative Disorders (CMPD)**

CMPD are a group of slow growing blood cancers in which the bone marrow makes too many red blood cells, white blood cells, or platelets. In myeloproliferative disorders, too many blood stem cells become one or more types of blood cells. There are 6 types of chronic myeloproliferative disorders, including chronic myelogenous leukemia, Polycythemia vera, Primary myelofibrosis, Essential thrombocythemia, chronic neutrophilic leukemia, and chronic eosinophilic leukemia. Although genetic (Philadelphia chromosome and BDR/abl) and molecular studies (Jak2) are the accepted cornerstone for the identification and classification of CMPDs Flow cytometry may assist in the distinction from reactive hematopoietic proliferations and is important in the enumeration of blasts in the distinction from acute leukemia and an accelerated phase of CMPS. CMPS also has a definite risk and rate of progression to acute leukemia. Standard flow cytometry leukemia panels are indicated to evaluate the progression and onset of leukemia.

21. **Minimal Residual Disease (MRD)**

Flow cytometry analysis for MRD identifies phenotypic features characteristic of the disease of interest. The MRD flow analysis should not rely on an exact match between the phenotype of the residual disease and the original diagnostic specimen because phenotypes can change over time and with treatment. The antibody combinations should be chosen to maximize detection of disease, limit the impact of phenotypic variation, and permit detection of disease following antibody directed therapy. In patients with acute leukemia, studies of minimal residual disease (MRD) provide powerful and independent prognostic information. Multiparameter flow cytometry is a widely applicable and reliable approach for monitoring MRD. Using triple or quadruple marker combinations, aberrant or uncommon phenotypic profiles can be identified in about 80% of patients with acute myeloid leukemia (AML) and 95% of patients with acute lymphoblastic leukemia (ALL). (Vidruales)

Indications - DNA Analysis

1. **Molar Pregnancies (Hydatidiform Mole)**
Flow cytometry has also been proven to be useful in evaluating molar and partial molar pregnancies. Using a method to quantify DNA, similar to that used for evaluation of carcinomas, partial moles, which are triploid, can be readily distinguished from normal placenta and complete molar pregnancies (which are usually diploid). This is a very important clinical distinction and is a valid indication for flow cytometry.
2. **Carcinomas**

DNA analysis of tumor for ploidy and percent-S-phase cells may be necessary for selective patients with carcinomas. Information obtained from flow cytometry is useful when the obtained prognostic information will affect treatment decisions in patients with low stage (localized disease). This is usually performed only one time after a diagnosis has been made and before treatment is initiated. These tests are not indicated for prognostic and therapeutic purposes in the routine clinical management of cancers. Some of the reasons for this are: Ploidy status may have uncertain value in individual patients depending on a number of factors that can include specimen size, source, and preparation; and that aneuploidy has been detected in non-tumor cells.

Increased S-phase activity is a more accepted prognostic indicator but it is technically more difficult to measure accurately. Not all tumors with S-phase fraction are malignant; not all tumors with increased S-phase metastasize; and not all malignant tumors with relatively small S-phase fraction fail to metastasize. It has not been proven that this testing provides useful information in colorectal or breast cancers.It has not been proven that this testing provides useful information in colorectal or breast cancers.

This testing is indicated for selected patients (without metastatic disease) with the following conditions:
a. Prostatic adenocarcinoma
b. Urinary Bladder Carcinoma
c. Ovarian Carcinoma
d. Endometrial adenocarcinoma
e. Renal cell adenocarcinoma
f. Mediastinal neuroblastoma
g. Medulloblastoma

Summary of Evidence

N/A

Analysis of Evidence
(Rationale for Determination)

N/A

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Coding Information

Bill Type Codes:

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

N/A

Revenue Codes:

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

N/A

CPT/HCPCS Codes

Group 1 Paragraph:

N/A

Group 1 Codes:

88184	FLOW CYTOMETRY, CELL SURFACE, CYTOPLASMIC, OR NUCLEAR MARKER, TECHNICAL COMPONENT ONLY; FIRST MARKER
88185	FLOW CYTOMETRY, CELL SURFACE, CYTOPLASMIC, OR NUCLEAR MARKER, TECHNICAL COMPONENT ONLY; EACH ADDITIONAL MARKER (LIST SEPARATELY IN ADDITION TO CODE FOR FIRST MARKER)
88187	FLOW CYTOMETRY, INTERPRETATION; 2 TO 8 MARKERS
88188	FLOW CYTOMETRY, INTERPRETATION; 9 TO 15 MARKERS
88189	FLOW CYTOMETRY, INTERPRETATION; 16 OR MORE MARKERS

Group 2 Paragraph:

N/A

Group 2 Codes:

88182 FLOW CYTOMETRY, CELL CYCLE OR DNA ANALYSIS

ICD-10 Codes that Support Medical Necessity

Group 1 Paragraph:

Note: diagnosis codes must be coded to the highest level of specificity.

Covered for:

CPT codes 88184-88189 are indicated for the following conditions:

Group 1 Codes:

ICD-10 Codes	Description
B20	Human immunodeficiency virus [HIV] disease
B97.33	Human T-cell lymphotrophic virus, type I [HTLV-I] as the cause of diseases classified elsewhere

ICD-10 Codes	Description
B97.34	Human T-cell lymphotrophic virus, type II [HTLV-II] as the cause of diseases classified elsewhere
B97.35	Human immunodeficiency virus, type 2 [HIV 2] as the cause of diseases classified elsewhere
C77.0 - C77.9	Secondary and unspecified malignant neoplasm of lymph nodes of head, face and neck - Secondary and unspecified malignant neoplasm of lymph node, unspecified
C80.0	Disseminated malignant neoplasm, unspecified
C80.1	Malignant (primary) neoplasm, unspecified
C81.00	Nodular lymphocyte predominant Hodgkin lymphoma, unspecified site
C81.01 - C81.09	Nodular lymphocyte predominant Hodgkin lymphoma, lymph nodes of head, face, and neck - Nodular lymphocyte predominant Hodgkin lymphoma, extranodal and solid organ sites
C81.10 - C81.19	Nodular sclerosis Hodgkin lymphoma, unspecified site - Nodular sclerosis Hodgkin lymphoma, extranodal and solid organ sites
C81.20 - C81.29	Mixed cellularity Hodgkin lymphoma, unspecified site - Mixed cellularity Hodgkin lymphoma, extranodal and solid organ sites
C81.30 - C81.39	Lymphocyte depleted Hodgkin lymphoma, unspecified site - Lymphocyte depleted Hodgkin lymphoma, extranodal and solid organ sites
C81.40 - C81.49	Lymphocyte-rich Hodgkin lymphoma, unspecified site - Lymphocyte-rich Hodgkin lymphoma, extranodal and solid organ sites
C81.70 - C81.79	Other Hodgkin lymphoma, unspecified site - Other Hodgkin lymphoma, extranodal and solid organ sites
C81.90 - C81.99	Hodgkin lymphoma, unspecified, unspecified site - Hodgkin lymphoma, unspecified, extranodal and solid organ sites
C82.00 - C82.09	Follicular lymphoma grade I, unspecified site - Follicular lymphoma grade I, extranodal and solid organ sites
C82.10 - C82.19	Follicular lymphoma grade II, unspecified site - Follicular lymphoma grade II, extranodal and solid organ sites
C82.20 - C82.29	Follicular lymphoma grade III, unspecified, unspecified site - Follicular lymphoma grade III, unspecified, extranodal and solid organ sites
C82.30 - C82.39	Follicular lymphoma grade IIIa, unspecified site - Follicular lymphoma grade IIIa, extranodal and solid organ sites
C82.40 - C82.49	Follicular lymphoma grade IIIb, unspecified site - Follicular lymphoma grade IIIb, extranodal and solid organ sites
C82.50 - C82.59	Diffuse follicle center lymphoma, unspecified site - Diffuse follicle center lymphoma, extranodal and solid organ sites
C82.60 - C82.69	Cutaneous follicle center lymphoma, unspecified site - Cutaneous follicle center lymphoma, extranodal and solid organ sites
C82.80 - C82.89	Other types of follicular lymphoma, unspecified site - Other types of follicular lymphoma, extranodal and solid organ sites
C82.90 - C82.99	Follicular lymphoma, unspecified, unspecified site - Follicular lymphoma, unspecified, extranodal and solid organ sites
C83.00 - C83.09	Small cell B-cell lymphoma, unspecified site - Small cell B-cell lymphoma, extranodal and solid organ sites
C83.10 - C83.19	Mantle cell lymphoma, unspecified site - Mantle cell lymphoma, extranodal and solid organ sites
C83.30 - C83.39	Diffuse large B-cell lymphoma, unspecified site - Diffuse large B-cell lymphoma, extranodal and solid organ sites
C83.50 - C83.59	Lymphoblastic (diffuse) lymphoma, unspecified site - Lymphoblastic (diffuse) lymphoma, extranodal and solid organ sites
C83.70 - C83.79	Burkitt lymphoma, unspecified site - Burkitt lymphoma, extranodal and solid organ sites
C83.80 - C83.89	Other non-follicular lymphoma, unspecified site - Other non-follicular lymphoma, extranodal and solid organ sites
C83.90 - C83.99	Non-follicular (diffuse) lymphoma, unspecified, unspecified site - Non-follicular (diffuse) lymphoma, unspecified, extranodal and solid organ sites
C84.00 - C84.09	Mycosis fungoides, unspecified site - Mycosis fungoides, extranodal and solid organ sites
C84.10 - C84.19	Sezary disease, unspecified site - Sezary disease, extranodal and solid organ sites
C84.40 - C84.49	Peripheral T-cell lymphoma, not classified, unspecified site - Peripheral T-cell lymphoma, not classified, extranodal and solid organ sites
C84.60 - C84.69	Anaplastic large cell lymphoma, ALK-positive, unspecified site - Anaplastic large cell lymphoma, ALK -positive, extranodal and solid organ sites

ICD-10 Codes	Description
C84.70 - C84.79	Anaplastic large cell lymphoma, ALK-negative, unspecified site - Anaplastic large cell lymphoma, ALK-negative, extranodal and solid organ sites
C84.A0 - C84.A9	Cutaneous T-cell lymphoma, unspecified, unspecified site - Cutaneous T-cell lymphoma, unspecified, extranodal and solid organ sites
C84.Z0	Other mature T/NK-cell lymphomas, unspecified site
C84.Z1	Other mature T/NK-cell lymphomas, lymph nodes of head, face, and neck
C84.Z2	Other mature T/NK-cell lymphomas, intrathoracic lymph nodes
C84.Z3	Other mature T/NK-cell lymphomas, intra-abdominal lymph nodes
C84.Z4	Other mature T/NK-cell lymphomas, lymph nodes of axilla and upper limb
C84.Z5	Other mature T/NK-cell lymphomas, lymph nodes of inguinal region and lower limb
C84.Z6	Other mature T/NK-cell lymphomas, intrapelvic lymph nodes
C84.Z7	Other mature T/NK-cell lymphomas, spleen
C84.Z8	Other mature T/NK-cell lymphomas, lymph nodes of multiple sites
C84.Z9	Other mature T/NK-cell lymphomas, extranodal and solid organ sites
C84.90 - C84.99	Mature T/NK-cell lymphomas, unspecified, unspecified site - Mature T/NK-cell lymphomas, unspecified, extranodal and solid organ sites
C85.10 - C85.19	Unspecified B-cell lymphoma, unspecified site - Unspecified B-cell lymphoma, extranodal and solid organ sites
C85.20 - C85.29	Mediastinal (thymic) large B-cell lymphoma, unspecified site - Mediastinal (thymic) large B-cell lymphoma, extranodal and solid organ sites
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
C85.90 - C85.99	Non-Hodgkin lymphoma, unspecified, unspecified site - Non-Hodgkin lymphoma, unspecified, extranodal and solid organ sites
C86.0	Extranodal NK/T-cell lymphoma, nasal type
C86.1	Hepatosplenic T-cell lymphoma
C86.2	Enteropathy-type (intestinal) T-cell lymphoma
C86.3	Subcutaneous panniculitis-like T-cell lymphoma
C86.4	Blastic NK-cell lymphoma
C86.5	Angioimmunoblastic T-cell lymphoma
C86.6	Primary cutaneous CD30-positive T-cell proliferations
C88.0	Waldenstrom macroglobulinemia
C88.2	Heavy chain disease
C88.3	Immunoproliferative small intestinal disease
C88.4	Extranodal marginal zone B-cell lymphoma of mucosa-associated lymphoid tissue [MALT-lymphoma]
C88.8	Other malignant immunoproliferative diseases
C90.00	Multiple myeloma not having achieved remission
C90.01	Multiple myeloma in remission
C90.02	Multiple myeloma in relapse
C90.10	Plasma cell leukemia not having achieved remission
C90.11	Plasma cell leukemia in remission
C90.12	Plasma cell leukemia in relapse
C90.20	Extramedullary plasmacytoma not having achieved remission
C90.21	Extramedullary plasmacytoma in remission
C90.22	Extramedullary plasmacytoma in relapse
C90.30	Solitary plasmacytoma not having achieved remission
C90.31	Solitary plasmacytoma in remission
C90.32	Solitary plasmacytoma in relapse
C91.00	Acute lymphoblastic leukemia not having achieved remission
C91.01	Acute lymphoblastic leukemia, in remission
C91.02	Acute lymphoblastic leukemia, in relapse
C91.10	Chronic lymphocytic leukemia of B-cell type not having achieved remission
C91.11	Chronic lymphocytic leukemia of B-cell type in remission
C91.12	Chronic lymphocytic leukemia of B-cell type in relapse
C91.30	Prolymphocytic leukemia of B-cell type not having achieved remission
C91.31	Prolymphocytic leukemia of B-cell type, in remission
C91.32	Prolymphocytic leukemia of B-cell type, in relapse

ICD-10 Codes	Description
C91.40	Hairy cell leukemia not having achieved remission
C91.41	Hairy cell leukemia, in remission
C91.42	Hairy cell leukemia, in relapse
C91.50	Adult T-cell lymphoma/leukemia (HTLV-1-associated) not having achieved remission
C91.51	Adult T-cell lymphoma/leukemia (HTLV-1-associated), in remission
C91.52	Adult T-cell lymphoma/leukemia (HTLV-1-associated), in relapse
C91.60	Prolymphocytic leukemia of T-cell type not having achieved remission
C91.61	Prolymphocytic leukemia of T-cell type, in remission
C91.62	Prolymphocytic leukemia of T-cell type, in relapse
C91.A0	Mature B-cell leukemia Burkitt-type not having achieved remission
C91.A1	Mature B-cell leukemia Burkitt-type, in remission
C91.A2	Mature B-cell leukemia Burkitt-type, in relapse
C91.Z0	Other lymphoid leukemia not having achieved remission
C91.Z1	Other lymphoid leukemia, in remission
C91.Z2	Other lymphoid leukemia, in relapse
C91.90	Lymphoid leukemia, unspecified not having achieved remission
C91.91	Lymphoid leukemia, unspecified, in remission
C91.92	Lymphoid leukemia, unspecified, in relapse
C92.00	Acute myeloblastic leukemia, not having achieved remission
C92.01	Acute myeloblastic leukemia, in remission
C92.02	Acute myeloblastic leukemia, in relapse
C92.10	Chronic myeloid leukemia, BCR/ABL-positive, not having achieved remission
C92.11	Chronic myeloid leukemia, BCR/ABL-positive, in remission
C92.12	Chronic myeloid leukemia, BCR/ABL-positive, in relapse
C92.20	Atypical chronic myeloid leukemia, BCR/ABL-negative, not having achieved remission
C92.21	Atypical chronic myeloid leukemia, BCR/ABL-negative, in remission
C92.22	Atypical chronic myeloid leukemia, BCR/ABL-negative, in relapse
C92.30	Myeloid sarcoma, not having achieved remission
C92.31	Myeloid sarcoma, in remission
C92.32	Myeloid sarcoma, in relapse
C92.40	Acute promyelocytic leukemia, not having achieved remission
C92.41	Acute promyelocytic leukemia, in remission
C92.42	Acute promyelocytic leukemia, in relapse
C92.50	Acute myelomonocytic leukemia, not having achieved remission
C92.51	Acute myelomonocytic leukemia, in remission
C92.52	Acute myelomonocytic leukemia, in relapse
C92.60	Acute myeloid leukemia with 11q23-abnormality not having achieved remission
C92.61	Acute myeloid leukemia with 11q23-abnormality in remission
C92.62	Acute myeloid leukemia with 11q23-abnormality in relapse
C92.A0	Acute myeloid leukemia with multilineage dysplasia, not having achieved remission
C92.A1	Acute myeloid leukemia with multilineage dysplasia, in remission
C92.A2	Acute myeloid leukemia with multilineage dysplasia, in relapse
C92.Z0	Other myeloid leukemia not having achieved remission
C92.Z1	Other myeloid leukemia, in remission
C92.Z2	Other myeloid leukemia, in relapse
C92.90	Myeloid leukemia, unspecified, not having achieved remission
C92.91	Myeloid leukemia, unspecified in remission
C92.92	Myeloid leukemia, unspecified in relapse
C93.00	Acute monoblastic/monocytic leukemia, not having achieved remission
C93.01	Acute monoblastic/monocytic leukemia, in remission
C93.02	Acute monoblastic/monocytic leukemia, in relapse
C93.10	Chronic myelomonocytic leukemia not having achieved remission
C93.11	Chronic myelomonocytic leukemia, in remission
C93.12	Chronic myelomonocytic leukemia, in relapse
C93.30	Juvenile myelomonocytic leukemia, not having achieved remission
C93.31	Juvenile myelomonocytic leukemia, in remission
C93.32	Juvenile myelomonocytic leukemia, in relapse
C93.Z0	Other monocytic leukemia, not having achieved remission

ICD-10 Codes	Description
C93.Z1	Other monocytic leukemia, in remission
C93.Z2	Other monocytic leukemia, in relapse
C93.90	Monocytic leukemia, unspecified, not having achieved remission
C93.91	Monocytic leukemia, unspecified in remission
C93.92	Monocytic leukemia, unspecified in relapse
C94.00	Acute erythroid leukemia, not having achieved remission
C94.01	Acute erythroid leukemia, in remission
C94.02	Acute erythroid leukemia, in relapse
C94.20	Acute megakaryoblastic leukemia not having achieved remission
C94.21	Acute megakaryoblastic leukemia, in remission
C94.22	Acute megakaryoblastic leukemia, in relapse
C94.30	Mast cell leukemia not having achieved remission
C94.31	Mast cell leukemia, in remission
C94.32	Mast cell 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 classified
C94.80	Other specified leukemias not having achieved remission
C94.81	Other specified leukemias, in remission
C94.82	Other specified leukemias, in relapse
C95.00	Acute leukemia of unspecified cell type not having achieved remission
C95.01	Acute leukemia of unspecified cell type, in remission
C95.02	Acute leukemia of unspecified cell type, in relapse
C95.10	Chronic leukemia of unspecified cell type not having achieved remission
C95.11	Chronic leukemia of unspecified cell type, in remission
C95.12	Chronic leukemia of unspecified cell type, in relapse
C95.90	Leukemia, unspecified not having achieved remission
C95.91	Leukemia, unspecified, in remission
C95.92	Leukemia, unspecified, in relapse
C96.0	Multifocal and multisystemic (disseminated) Langerhans-cell histiocytosis
C96.20	Malignant mast cell neoplasm, unspecified
C96.21	Aggressive systemic mastocytosis
C96.22	Mast cell sarcoma
C96.29	Other malignant mast cell neoplasm
C96.4	Sarcoma of dendritic cells (accessory cells)
C96.5	Multifocal and unisystemic Langerhans-cell histiocytosis
C96.6	Unifocal Langerhans-cell histiocytosis
C96.A	Histiocytic sarcoma
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
D47.01	Cutaneous mastocytosis
D47.02	Systemic mastocytosis
D47.09	Other mast cell neoplasms of uncertain behavior
D47.1	Chronic myeloproliferative disease

ICD-10 Codes	Description
D47.2	Monoclonal gammopathy
D47.3	Essential (hemorrhagic) thrombocythemia
D47.Z1	Post-transplant lymphoproliferative disorder (PTLD)
D47.Z9	Other specified neoplasms of uncertain behavior of lymphoid, hematopoietic and related tissue
D56.0	Alpha thalassemia
D56.1	Beta thalassemia
D56.2	Delta-beta thalassemia
D56.3	Thalassemia minor
D56.4	Hereditary persistence of fetal hemoglobin [HPFH]
D56.5	Hemoglobin E-beta thalassemia
D56.8	Other thalassemias
D57.01	Hb-SS disease with acute chest syndrome
D57.02	Hb-SS disease with splenic sequestration
D57.1	Sickle-cell disease without crisis
D57.20	Sickle-cell/Hb-C disease without crisis
D57.211	Sickle-cell/Hb-C disease with acute chest syndrome
D57.212	Sickle-cell/Hb-C disease with splenic sequestration
D57.219	Sickle-cell/Hb-C disease with crisis, unspecified
D57.3	Sickle-cell trait
D57.411	Sickle-cell thalassemia with acute chest syndrome
D57.412	Sickle-cell thalassemia with splenic sequestration
D57.80	Other sickle-cell disorders without crisis
D57.811	Other sickle-cell disorders with acute chest syndrome
D57.812	Other sickle-cell disorders with splenic sequestration
D57.819	Other sickle-cell disorders with crisis, unspecified
D58.0	Hereditary spherocytosis
D58.1	Hereditary elliptocytosis
D58.2	Other hemoglobinopathies
D59.5	Paroxysmal nocturnal hemoglobinuria [Marchiafava-Micheli]
D59.6	Hemoglobinuria due to hemolysis from other external causes
D59.8	Other acquired hemolytic anemias
D59.9	Acquired hemolytic anemia, unspecified
D60.0	Chronic acquired pure red cell aplasia
D60.1	Transient acquired pure red cell aplasia
D60.8	Other acquired pure red cell aplasias
D61.01	Constitutional (pure) red blood cell aplasia
D61.09	Other constitutional aplastic anemia
D61.1	Drug-induced aplastic anemia
D61.2	Aplastic anemia due to other external agents
D61.3	Idiopathic aplastic anemia
D61.810	Antineoplastic chemotherapy induced pancytopenia
D61.811	Other drug-induced pancytopenia
D61.818	Other pancytopenia
D61.82	Myelophthisis
D61.89	Other specified aplastic anemias and other bone marrow failure syndromes
D61.9	Aplastic anemia, unspecified
D63.0	Anemia in neoplastic disease
D64.0	Hereditary sideroblastic anemia
D64.1	Secondary sideroblastic anemia due to disease
D64.2	Secondary sideroblastic anemia due to drugs and toxins
D64.3	Other sideroblastic anemias
D64.4	Congenital dyserythropoietic anemia
D64.89	Other specified anemias
D64.9	Anemia, unspecified
D69.1	Qualitative platelet defects
D69.3	Immune thrombocytopenic purpura
D69.41	Evans syndrome
D69.42	Congenital and hereditary thrombocytopenia purpura

ICD-10 Codes	Description
D69.49	Other primary thrombocytopenia
D69.51	Posttransfusion purpura
D69.59	Other secondary thrombocytopenia
D69.6	Thrombocytopenia, unspecified
D70.0	Congenital agranulocytosis
D70.1	Agranulocytosis secondary to cancer chemotherapy
D70.2	Other drug-induced agranulocytosis
D70.3	Neutropenia due to infection
D70.4	Cyclic neutropenia
D70.8	Other neutropenia
D70.9	Neutropenia, unspecified
D71	Functional disorders of polymorphonuclear neutrophils
D72.0	Genetic anomalies of leukocytes
D72.1	Eosinophilia
D72.810	Lymphocytopenia
D72.818	Other decreased white blood cell count
D72.819	Decreased white blood cell count, unspecified
D72.820	Lymphocytosis (symptomatic)
D72.821	Monocytosis (symptomatic)
D72.822	Plasmacytosis
D72.823	Leukemoid reaction
D72.824	Basophilia
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
D73.1	Hypersplenism
D73.81	Neutropenic splenomegaly
D75.81	Myelofibrosis
D75.9	Disease of blood and blood-forming organs, unspecified
D76.1	Hemophagocytic lymphohistiocytosis
D76.2	Hemophagocytic syndrome, infection-associated
D76.3	Other histiocytosis syndromes
D80.0	Hereditary hypogammaglobulinemia
D80.1	Nonfamilial hypogammaglobulinemia
D80.2	Selective deficiency of immunoglobulin A [IgA]
D80.3	Selective deficiency of immunoglobulin G [IgG] subclasses
D80.4	Selective deficiency of immunoglobulin M [IgM]
D80.5	Immunodeficiency with increased immunoglobulin M [IgM]
D80.6	Antibody deficiency with near-normal immunoglobulins or with hyperimmunoglobulinemia
D80.7	Transient hypogammaglobulinemia of infancy
D80.8	Other immunodeficiencies with predominantly antibody defects
D81.0	Severe combined immunodeficiency [SCID] with reticular dysgenesis
D81.1	Severe combined immunodeficiency [SCID] with low T- and B-cell numbers
D81.2	Severe combined immunodeficiency [SCID] with low or normal B-cell numbers
D81.4	Nezelof's syndrome
D81.6	Major histocompatibility complex class I deficiency
D81.7	Major histocompatibility complex class II deficiency
D81.89	Other combined immunodeficiencies
D82.0	Wiskott-Aldrich syndrome
D82.1	Di George's syndrome
D82.2	Immunodeficiency with short-limbed stature
D82.3	Immunodeficiency following hereditary defective response to Epstein-Barr virus
D82.4	Hyperimmunoglobulin E [IgE] syndrome
D82.8	Immunodeficiency associated with other specified major defects
D83.0	Common variable immunodeficiency with predominant abnormalities of B-cell numbers and function
D83.1	Common variable immunodeficiency with predominant immunoregulatory T-cell disorders
D83.2	Common variable immunodeficiency with autoantibodies to B- or T-cells

ICD-10 Codes	Description
D83.8	Other common variable immunodeficiencies
D83.9	Common variable immunodeficiency, unspecified
D84.0	Lymphocyte function antigen-1 [LFA-1] defect
D84.1	Defects in the complement system
D84.8	Other specified immunodeficiencies
D89.1	Cryoglobulinemia
D89.2	Hypergammaglobulinemia, unspecified
D89.3	Immune reconstitution syndrome
D89.810	Acute graft-versus-host disease
D89.811	Chronic graft-versus-host disease
D89.812	Acute on chronic graft-versus-host disease
D89.813	Graft-versus-host disease, unspecified
D89.82	Autoimmune lymphoproliferative syndrome [ALPS]
D89.89	Other specified disorders involving the immune mechanism, not elsewhere classified
D89.9	Disorder involving the immune mechanism, unspecified
E88.09	Other disorders of plasma-protein metabolism, not elsewhere classified
G11.3	Cerebellar ataxia with defective DNA repair
G11.8	Other hereditary ataxias
H20.9	Unspecified iridocyclitis
I81	Portal vein thrombosis
I82.91	Chronic embolism and thrombosis of unspecified vein
I88.0	Nonspecific mesenteric lymphadenitis
I88.1	Chronic lymphadenitis, except mesenteric
I88.8	Other nonspecific lymphadenitis
K50.00	Crohn's disease of small intestine without complications
K50.011	Crohn's disease of small intestine with rectal bleeding
K50.012	Crohn's disease of small intestine with intestinal obstruction
K50.013	Crohn's disease of small intestine with fistula
K50.014	Crohn's disease of small intestine with abscess
K50.018	Crohn's disease of small intestine with other complication
K50.10	Crohn's disease of large intestine without complications
K50.111	Crohn's disease of large intestine with rectal bleeding
K50.112	Crohn's disease of large intestine with intestinal obstruction
K50.113	Crohn's disease of large intestine with fistula
K50.114	Crohn's disease of large intestine with abscess
K50.118	Crohn's disease of large intestine with other complication
K50.80	Crohn's disease of both small and large intestine without complications
K50.811	Crohn's disease of both small and large intestine with rectal bleeding
K50.812	Crohn's disease of both small and large intestine with intestinal obstruction
K50.813	Crohn's disease of both small and large intestine with fistula
K50.814	Crohn's disease of both small and large intestine with abscess
K50.818	Crohn's disease of both small and large intestine with other complication
K50.90	Crohn's disease, unspecified, without complications
K50.911	Crohn's disease, unspecified, with rectal bleeding
K50.912	Crohn's disease, unspecified, with intestinal obstruction
K50.913	Crohn's disease, unspecified, with fistula
K50.914	Crohn's disease, unspecified, with abscess
K50.918	Crohn's disease, unspecified, with other complication
K51.00	Ulcerative (chronic) pancolitis without complications
K51.011	Ulcerative (chronic) pancolitis with rectal bleeding
K51.012	Ulcerative (chronic) pancolitis with intestinal obstruction
K51.013	Ulcerative (chronic) pancolitis with fistula
K51.014	Ulcerative (chronic) pancolitis with abscess
K51.018	Ulcerative (chronic) pancolitis with other complication
K51.20	Ulcerative (chronic) proctitis without complications
K51.211	Ulcerative (chronic) proctitis with rectal bleeding
K51.212	Ulcerative (chronic) proctitis with intestinal obstruction
K51.213	Ulcerative (chronic) proctitis with fistula

ICD-10 Codes	Description
K51.214	Ulcerative (chronic) proctitis with abscess
K51.218	Ulcerative (chronic) proctitis with other complication
K51.30	Ulcerative (chronic) rectosigmoiditis without complications
K51.311	Ulcerative (chronic) rectosigmoiditis with rectal bleeding
K51.312	Ulcerative (chronic) rectosigmoiditis with intestinal obstruction
K51.313	Ulcerative (chronic) rectosigmoiditis with fistula
K51.314	Ulcerative (chronic) rectosigmoiditis with abscess
K51.318	Ulcerative (chronic) rectosigmoiditis with other complication
K51.40	Inflammatory polyps of colon without complications
K51.411	Inflammatory polyps of colon with rectal bleeding
K51.412	Inflammatory polyps of colon with intestinal obstruction
K51.413	Inflammatory polyps of colon with fistula
K51.414	Inflammatory polyps of colon with abscess
K51.418	Inflammatory polyps of colon with other complication
K51.50	Left sided colitis without complications
K51.511	Left sided colitis with rectal bleeding
K51.512	Left sided colitis with intestinal obstruction
K51.513	Left sided colitis with fistula
K51.514	Left sided colitis with abscess
K51.518	Left sided colitis with other complication
K51.80	Other ulcerative colitis without complications
K51.811	Other ulcerative colitis with rectal bleeding
K51.812	Other ulcerative colitis with intestinal obstruction
K51.813	Other ulcerative colitis with fistula
K51.814	Other ulcerative colitis with abscess
K51.818	Other ulcerative colitis with other complication
K51.90	Ulcerative colitis, unspecified, without complications
K51.911	Ulcerative colitis, unspecified with rectal bleeding
K51.912	Ulcerative colitis, unspecified with intestinal obstruction
K51.913	Ulcerative colitis, unspecified with fistula
K51.914	Ulcerative colitis, unspecified with abscess
K51.918	Ulcerative colitis, unspecified with other complication
L40.50	Arthropathic psoriasis, unspecified
L40.51	Distal interphalangeal psoriatic arthropathy
L40.52	Psoriatic arthritis mutilans
L40.53	Psoriatic spondylitis
L40.54	Psoriatic juvenile arthropathy
L40.59	Other psoriatic arthropathy
M02.30	Reiter's disease, unspecified site
M02.311	Reiter's disease, right shoulder
M02.312	Reiter's disease, left shoulder
M02.321	Reiter's disease, right elbow
M02.322	Reiter's disease, left elbow
M02.331	Reiter's disease, right wrist
M02.332	Reiter's disease, left wrist
M02.341	Reiter's disease, right hand
M02.342	Reiter's disease, left hand
M02.351	Reiter's disease, right hip
M02.352	Reiter's disease, left hip
M02.361	Reiter's disease, right knee
M02.362	Reiter's disease, left knee
M02.371	Reiter's disease, right ankle and foot
M02.372	Reiter's disease, left ankle and foot
M02.38	Reiter's disease, vertebrae
M02.39	Reiter's disease, multiple sites
M08.00	Unspecified juvenile rheumatoid arthritis of unspecified site
M08.011	Unspecified juvenile rheumatoid arthritis, right shoulder

ICD-10 Codes	Description
M08.012	Unspecified juvenile rheumatoid arthritis, left shoulder
M08.021	Unspecified juvenile rheumatoid arthritis, right elbow
M08.022	Unspecified juvenile rheumatoid arthritis, left elbow
M08.031	Unspecified juvenile rheumatoid arthritis, right wrist
M08.032	Unspecified juvenile rheumatoid arthritis, left wrist
M08.041	Unspecified juvenile rheumatoid arthritis, right hand
M08.042	Unspecified juvenile rheumatoid arthritis, left hand
M08.051	Unspecified juvenile rheumatoid arthritis, right hip
M08.052	Unspecified juvenile rheumatoid arthritis, left hip
M08.061	Unspecified juvenile rheumatoid arthritis, right knee
M08.062	Unspecified juvenile rheumatoid arthritis, left knee
M08.071	Unspecified juvenile rheumatoid arthritis, right ankle and foot
M08.072	Unspecified juvenile rheumatoid arthritis, left ankle and foot
M08.08	Unspecified juvenile rheumatoid arthritis, vertebrae
M08.09	Unspecified juvenile rheumatoid arthritis, multiple sites
M08.1	Juvenile ankylosing spondylitis
M08.211	Juvenile rheumatoid arthritis with systemic onset, right shoulder
M08.212	Juvenile rheumatoid arthritis with systemic onset, left shoulder
M08.221	Juvenile rheumatoid arthritis with systemic onset, right elbow
M08.222	Juvenile rheumatoid arthritis with systemic onset, left elbow
M08.231	Juvenile rheumatoid arthritis with systemic onset, right wrist
M08.232	Juvenile rheumatoid arthritis with systemic onset, left wrist
M08.241	Juvenile rheumatoid arthritis with systemic onset, right hand
M08.242	Juvenile rheumatoid arthritis with systemic onset, left hand
M08.251	Juvenile rheumatoid arthritis with systemic onset, right hip
M08.252	Juvenile rheumatoid arthritis with systemic onset, left hip
M08.261	Juvenile rheumatoid arthritis with systemic onset, right knee
M08.262	Juvenile rheumatoid arthritis with systemic onset, left knee
M08.271	Juvenile rheumatoid arthritis with systemic onset, right ankle and foot
M08.272	Juvenile rheumatoid arthritis with systemic onset, left ankle and foot
M08.28	Juvenile rheumatoid arthritis with systemic onset, vertebrae
M08.29	Juvenile rheumatoid arthritis with systemic onset, multiple sites
M08.3	Juvenile rheumatoid polyarthritis (seronegative)
M08.811	Other juvenile arthritis, right shoulder
M08.812	Other juvenile arthritis, left shoulder
M08.821	Other juvenile arthritis, right elbow
M08.822	Other juvenile arthritis, left elbow
M08.831	Other juvenile arthritis, right wrist
M08.832	Other juvenile arthritis, left wrist
M08.841	Other juvenile arthritis, right hand
M08.842	Other juvenile arthritis, left hand
M08.851	Other juvenile arthritis, right hip
M08.852	Other juvenile arthritis, left hip
M08.861	Other juvenile arthritis, right knee
M08.862	Other juvenile arthritis, left knee
M08.871	Other juvenile arthritis, right ankle and foot
M08.872	Other juvenile arthritis, left ankle and foot
M08.88	Other juvenile arthritis, other specified site
M08.89	Other juvenile arthritis, multiple sites
M08.911	Juvenile arthritis, unspecified, right shoulder
M08.912	Juvenile arthritis, unspecified, left shoulder
M08.921	Juvenile arthritis, unspecified, right elbow
M08.922	Juvenile arthritis, unspecified, left elbow
M08.931	Juvenile arthritis, unspecified, right wrist
M08.932	Juvenile arthritis, unspecified, left wrist
M08.941	Juvenile arthritis, unspecified, right hand
M08.942	Juvenile arthritis, unspecified, left hand
M08.951	Juvenile arthritis, unspecified, right hip

ICD-10 Codes	Description
M08.952	Juvenile arthritis, unspecified, left hip
M08.959	Juvenile arthritis, unspecified, unspecified hip
M08.961	Juvenile arthritis, unspecified, right knee
M08.962	Juvenile arthritis, unspecified, left knee
M08.971	Juvenile arthritis, unspecified, right ankle and foot
M08.972	Juvenile arthritis, unspecified, left ankle and foot
M35.9	Systemic involvement of connective tissue, unspecified
M45.0	Ankylosing spondylitis of multiple sites in spine
M45.1	Ankylosing spondylitis of occipito-atlanto-axial region
M45.2	Ankylosing spondylitis of cervical region
M45.3	Ankylosing spondylitis of cervicothoracic region
M45.4	Ankylosing spondylitis of thoracic region
M45.5	Ankylosing spondylitis of thoracolumbar region
M45.6	Ankylosing spondylitis lumbar region
M45.7	Ankylosing spondylitis of lumbosacral region
M45.8	Ankylosing spondylitis sacral and sacrococcygeal region
M45.9	Ankylosing spondylitis of unspecified sites in spine
M46.00	Spinal enthesopathy, site unspecified
M46.01	Spinal enthesopathy, occipito-atlanto-axial region
M46.02	Spinal enthesopathy, cervical region
M46.03	Spinal enthesopathy, cervicothoracic region
M46.04	Spinal enthesopathy, thoracic region
M46.05	Spinal enthesopathy, thoracolumbar region
M46.06	Spinal enthesopathy, lumbar region
M46.07	Spinal enthesopathy, lumbosacral region
M46.08	Spinal enthesopathy, sacral and sacrococcygeal region
M46.09	Spinal enthesopathy, multiple sites in spine
M46.1	Sacroiliitis, not elsewhere classified
M46.50	Other infective spondylopathies, site unspecified
M46.51	Other infective spondylopathies, occipito-atlanto-axial region
M46.52	Other infective spondylopathies, cervical region
M46.53	Other infective spondylopathies, cervicothoracic region
M46.54	Other infective spondylopathies, thoracic region
M46.55	Other infective spondylopathies, thoracolumbar region
M46.56	Other infective spondylopathies, lumbar region
M46.57	Other infective spondylopathies, lumbosacral region
M46.58	Other infective spondylopathies, sacral and sacrococcygeal region
M46.59	Other infective spondylopathies, multiple sites in spine
M46.80	Other specified inflammatory spondylopathies, site unspecified
M46.81	Other specified inflammatory spondylopathies, occipito-atlanto-axial region
M46.82	Other specified inflammatory spondylopathies, cervical region
M46.83	Other specified inflammatory spondylopathies, cervicothoracic region
M46.84	Other specified inflammatory spondylopathies, thoracic region
M46.85	Other specified inflammatory spondylopathies, thoracolumbar region
M46.86	Other specified inflammatory spondylopathies, lumbar region
M46.87	Other specified inflammatory spondylopathies, lumbosacral region
M46.88	Other specified inflammatory spondylopathies, sacral and sacrococcygeal region
M46.89	Other specified inflammatory spondylopathies, multiple sites in spine
M46.90	Unspecified inflammatory spondylopathy, site unspecified
M46.91	Unspecified inflammatory spondylopathy, occipito-atlanto-axial region
M46.92	Unspecified inflammatory spondylopathy, cervical region
M46.93	Unspecified inflammatory spondylopathy, cervicothoracic region
M46.94	Unspecified inflammatory spondylopathy, thoracic region
M46.95	Unspecified inflammatory spondylopathy, thoracolumbar region
M46.96	Unspecified inflammatory spondylopathy, lumbar region
M46.97	Unspecified inflammatory spondylopathy, lumbosacral region
M46.98	Unspecified inflammatory spondylopathy, sacral and sacrococcygeal region

ICD-10 Codes	Description
M46.99	Unspecified inflammatory spondylopathy, multiple sites in spine
M48.8X1	Other specified spondylopathies, occipito-atlanto-axial region
M48.8X2	Other specified spondylopathies, cervical region
M48.8X3	Other specified spondylopathies, cervicothoracic region
M48.8X4	Other specified spondylopathies, thoracic region
M48.8X5	Other specified spondylopathies, thoracolumbar region
M48.8X6	Other specified spondylopathies, lumbar region
M48.8X7	Other specified spondylopathies, lumbosacral region
M48.8X8	Other specified spondylopathies, sacral and sacrococcygeal region
M49.80	Spondylopathy in diseases classified elsewhere, site unspecified
M49.81	Spondylopathy in diseases classified elsewhere, occipito-atlanto-axial region
M49.82	Spondylopathy in diseases classified elsewhere, cervical region
M49.83	Spondylopathy in diseases classified elsewhere, cervicothoracic region
M49.84	Spondylopathy in diseases classified elsewhere, thoracic region
M49.85	Spondylopathy in diseases classified elsewhere, thoracolumbar region
M49.86	Spondylopathy in diseases classified elsewhere, lumbar region
M49.87	Spondylopathy in diseases classified elsewhere, lumbosacral region
M49.88	Spondylopathy in diseases classified elsewhere, sacral and sacrococcygeal region
M49.89	Spondylopathy in diseases classified elsewhere, multiple sites in spine
R16.1	Splenomegaly, not elsewhere classified
R16.2	Hepatomegaly with splenomegaly, not elsewhere classified
R19.01	Right upper quadrant abdominal swelling, mass and lump
R19.02	Left upper quadrant abdominal swelling, mass and lump
R19.03	Right lower quadrant abdominal swelling, mass and lump
R19.04	Left lower quadrant abdominal swelling, mass and lump
R19.05	Periumbilic swelling, mass or lump
R19.06	Epigastric swelling, mass or lump
R19.07	Generalized intra-abdominal and pelvic swelling, mass and lump
R19.09	Other intra-abdominal and pelvic swelling, mass and lump
R59.0	Localized enlarged lymph nodes
R59.1	Generalized enlarged lymph nodes
R59.9	Enlarged lymph nodes, unspecified
R75	Inconclusive laboratory evidence of human immunodeficiency virus [HIV]
R80.0	Isolated proteinuria
R80.1	Persistent proteinuria, unspecified
R80.3	Bence Jones proteinuria
R80.8	Other proteinuria
R80.9	Proteinuria, unspecified
R89.7	Abnormal histological findings in specimens from other organs, systems and tissues
T86.01	Bone marrow transplant rejection
T86.02	Bone marrow transplant failure
T86.03	Bone marrow transplant infection
T86.09	Other complications of bone marrow transplant
T86.11	Kidney transplant rejection
T86.12	Kidney transplant failure
T86.13	Kidney transplant infection
T86.19	Other complication of kidney transplant
T86.21	Heart transplant rejection
T86.22	Heart transplant failure
T86.23	Heart transplant infection
T86.290	Cardiac allograft vasculopathy
T86.298	Other complications of heart transplant
T86.31	Heart-lung transplant rejection
T86.32	Heart-lung transplant failure
T86.33	Heart-lung transplant infection
T86.39	Other complications of heart-lung transplant
T86.41	Liver transplant rejection
T86.42	Liver transplant failure

ICD-10 Codes	Description
T86.43	Liver transplant infection
T86.49	Other complications of liver transplant
T86.5	Complications of stem cell transplant
T86.810	Lung transplant rejection
T86.811	Lung transplant failure
T86.812	Lung transplant infection
T86.818	Other complications of lung transplant
T86.850	Intestine transplant rejection
T86.851	Intestine transplant failure
T86.852	Intestine transplant infection
T86.858	Other complications of intestine transplant
T86.890	Other transplanted tissue rejection
T86.891	Other transplanted tissue failure
T86.892	Other transplanted tissue infection
T86.898	Other complications of other transplanted tissue
Z21	Asymptomatic human immunodeficiency virus [HIV] infection status
Z48.21	Encounter for aftercare following heart transplant
Z48.22	Encounter for aftercare following kidney transplant
Z48.23	Encounter for aftercare following liver transplant
Z48.24	Encounter for aftercare following lung transplant
Z48.280	Encounter for aftercare following heart-lung transplant
Z48.288	Encounter for aftercare following multiple organ transplant
Z48.290	Encounter for aftercare following bone marrow transplant
Z48.298	Encounter for aftercare following other organ transplant
Z79.899	Other long term (current) drug therapy
Z85.6	Personal history of leukemia
Z85.71	Personal history of Hodgkin lymphoma
Z85.72	Personal history of non-Hodgkin lymphomas
Z85.79	Personal history of other malignant neoplasms of lymphoid, hematopoietic and related tissues
Z94.0	Kidney transplant status
Z94.1	Heart transplant status
Z94.2	Lung transplant status
Z94.3	Heart and lungs transplant status
Z94.4	Liver transplant status
Z94.5	Skin transplant status
Z94.6	Bone transplant status
Z94.7	Corneal transplant status
Z94.81	Bone marrow transplant status
Z94.82	Intestine transplant status
Z94.83	Pancreas transplant status
Z94.84	Stem cells transplant status
Z94.89	Other transplanted organ and tissue status

Group 2 Paragraph:

CPT code 88182 (Flow cytometry, cell cycle or DNA analysis) is indicated for selected patients (without metastatic disease) with the following conditions:

Group 2 Codes:

ICD-10 Codes	Description
C38.1	Malignant neoplasm of anterior mediastinum
C38.2	Malignant neoplasm of posterior mediastinum
C54.1	Malignant neoplasm of endometrium
C54.2	Malignant neoplasm of myometrium
C54.3	Malignant neoplasm of fundus uteri

ICD-10 Codes	Description
C56.1	Malignant neoplasm of right ovary
C56.2	Malignant neoplasm of left ovary
C61	Malignant neoplasm of prostate
C64.1	Malignant neoplasm of right kidney, except renal pelvis
C64.2	Malignant neoplasm of left kidney, except renal pelvis
C64.9	Malignant neoplasm of unspecified kidney, except renal pelvis
C65.1	Malignant neoplasm of right renal pelvis
C65.2	Malignant neoplasm of left renal pelvis
C67.0	Malignant neoplasm of trigone of bladder
C67.1	Malignant neoplasm of dome of bladder
C67.2	Malignant neoplasm of lateral wall of bladder
C67.3	Malignant neoplasm of anterior wall of bladder
C67.4	Malignant neoplasm of posterior wall of bladder
C67.5	Malignant neoplasm of bladder neck
C67.6	Malignant neoplasm of ureteric orifice
C67.7	Malignant neoplasm of urachus
C67.8	Malignant neoplasm of overlapping sites of bladder
C67.9	Malignant neoplasm of bladder, unspecified
C71.0	Malignant neoplasm of cerebrum, except lobes and ventricles
C71.1	Malignant neoplasm of frontal lobe
C71.2	Malignant neoplasm of temporal lobe
C71.3	Malignant neoplasm of parietal lobe
C71.4	Malignant neoplasm of occipital lobe
C71.5	Malignant neoplasm of cerebral ventricle
C71.6	Malignant neoplasm of cerebellum
C71.7	Malignant neoplasm of brain stem
C71.8	Malignant neoplasm of overlapping sites of brain
O01.0	Classical hydatidiform mole
O01.1	Incomplete and partial hydatidiform mole

ICD-10 Codes that DO NOT Support Medical Necessity
Group 1 Paragraph:

N/A

Group 1 Codes: N/A

ICD-10 Additional Information Back to Top

General Information

Associated Information
Documentation Requirements
Adequate documentation is essential for high-quality patient care and to demonstrate the reasonableness and medical necessity of the procedure(s). Documentation must support the criteria for coverage as described in the Coverage Indications, Limitations, and/or Medical Necessity section of this LCD. There should be a permanent record of the performed studies including clinical and morphologic findings, cell counts (quantitative values), and radiology and cytogenetic findings when available and interpretation. Comparison with prior relevant imaging studies needs to be addressed in the documentation along with both normal and abnormal findings. Variations from normal size should be documented along with measurements. The report should address or answer any specific clinical questions. If there are factors that prevent answering the clinical questions, this should be explained in the documentation. Retention of the flow cytometry testing should be consistent both with clinical need and with relevant legal and local health care facility requirements.

If the provider of the study is other than the ordering/referring physician/nonphysician practitioner, that provider must maintain a copy of the test results and interpretation, along with copies of the ordering/referring

physician/nonphysician practitioner's order for the studies. This order is required to provide adequate diagnostic information to the performing provider. The physician/nonphysician practitioner must state the clinical indication/medical necessity for the study in his/her order for the test. The provider is responsible for ensuring the medical necessity of procedures and maintaining the medical record, which must be available to Medicare upon request. Results of all testing must be shared with the referring physician. Flow cytometry studies are medically reasonable and medically necessary only if the outcomes will be utilized in the clinical management of the patient.

Utilization Guidelines
Routine use of flow cytometry absent clinical indication for its use will be considered screening and will not be covered.

Routinely performing more than 20 analyses per specimen is not expected. When more than the stated makers (cell surface, cytoplasmic, or nuclear) are required, the documentation should support the medical necessity for the excess markers.

Up to 20 antibodies may be required to adequately characterize acute leukemia, chronic lymphoproliferative disorder (CLD), or lymphoma.

Up to 8 antibodies may be required to adequately characterize plasma cell dyscrasia.

Rare cases are diagnostic problems and may require more antibodies to characterize the disease process. Such problems should be documented in the patient's medical record.

Performing duplicate testing on different sources (i.e. blood smear and bone marrow) from the same patient in the same time frame may sometimes be necessary and the documentation must reflect the medical necessity.

Examples:
The lymph node flow cytometry is performed in order to render the diagnosis of lymphoma as well as subtype the malignancy, in order to "grade" the tumor. The bone marrow flow is done to "stage" the tumor by identifying malignancy within the bone marrow compartment. Both the grade and stage are separate data that are required prior to initiating appropriate therapy.

Similarly, flow may be performed on a lymph node and a pleural effusion, or a bone marrow and pleural effusion on the same day of service when the possibility of a malignant effusion is also suspected.

Flow cytometry used as part of experimental protocols is not a covered service.

Sources of Information
This bibliography represents the sources use to development the policy and additional resources used during times of review and/or revisions.

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Bibliography

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Revision History Information

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

Revision History Date	Revision History Number	Revision History Explanation	Reason(s) for Change
10/01/2017	R9	10/01/2017 ICD-10 CM Code updates: Group 1 deleted: C96.2. Group 1 added: C96.20, C96.21, C96.22, C96.29, D47.01, D47.02, D47.09.	• Revisions Due To ICD-10-CM Code Changes
09/01/2017	R8	09/01/2017 Annual review completed 08/10/2017. Reformatting IOM titles/verbiage references to match CMS updates. No change in coverage. 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.	• Other (Annual Review)
10/01/2016	R7	10/01/2016- Code update-description changes to C81.10-C81.19, C81.20-C81.29, C81.30-C81.39, C81.40-C81.49, C81.70-C81.79; formatting changes-ranged dx codes and moved 88182 into Group 2 Paragraph: Group 2 Codes. Annual review completed 09/01/2016- removed reference to stem cell NCD from CMS Coverage section; no change in coverage.	• Other (Annual Review) • Revisions Due To ICD-10-CM Code Changes
10/01/2015	R6	02/01/2016 Added C81.97, D59.9, D72.819, M46.91, M46.92, M46.93, M46.94, M46.95, M46.96, M46.97, M46.98, M46.99, R89.7, Z85.6, Z85.71, Z85.72, and Z85.79 to Group 1 and C67.9 to Group 2 effective 10/01/2015. Remove the CAC information.	• Revisions Due To ICD-10-CM Code Changes
10/01/2015	R5	11/01/2015 Added D83.9 to Group 1 Diagnostic codes. This code is effective 10/01/2015.	• Revisions Due To ICD-10-CM Code Changes
10/01/2015	R4	10/06/2015 - Due to CMS guidance, we have removed the Jurisdiction 8 Notice and corresponding table from the CMS National Coverage Policy section. No other changes to policy or coverage.	• Other
10/01/2015	R3	10/01/2015 - Corrected Typographical Error of the word Histiocytic and corrected numbering under Indications section.	• Typographical Error
10/01/2015	R2	10/01/2015 Annual review completed 09/02/2015. Added to Group 1 Diagnostic codes: C77.0-C77.5, C77.8, C77.9, C80.0, C80.1, C81.10, C81.20, C81.30, C81.40, C81.70, C81.90, C82.00, C82.10, C82.20-C82.30, C82.40, C82.50, C82.60, C82.80, C82.90-C82.97, C83.00, C83.10, C83.30, C83.50, C83.70, C83.80, C83.90, C83.92-C84.00. C84.10, C84.40, C84.60, C84.70, C84A0, C84.Z0, C84.90, C85.10-C85.13, C85.15-C85.18, C85.20, C85.80, C85.90, C93.90-C93.92, C96.5, C96.6, D46.4, D46.9, D56.0-D56.3, D56.5, D56.8, D57.219, D57.411, D57.412, D57.819, D58.1, D60.0, D60.1, D60.8, D61.810, D61.811, D61.9, D64.9, D69.6, D72.89, D73.1, D73.81, D75.81, D75.9, D80.0-D80.5, D80.7, D83.0, D83.2, D83.8, D89.1, D89.2, D89.813, E88.09, I88.0, I88.1, I88.8, M02.30, M08.00, M35.9, M45.9, M46.00, M46.50, M46.80, M46.90, R59.9, R80.0, R80.1, R80.3, R80.8, R80.9, and Z48.288. The following codes were removed from Group 1: A18.01, C88.9, D72.9, R19.00, R87.618, R89.7, T86.10, T86.30, T86.40, T86.830, T86.831, T86.832, T86.838, Z79.3, Z79.891, Z95.3, and Z95.4 because the condition is not addressed in the policy and the diagnosis was added in error. Updated and reformatted the CMS National Policy section. Documentation requirements were clarified. The sources of information had the web links removed.	• Other • Revisions Due To ICD-10-CM Code Changes
10/01/2015	R1	12/01/2014: Annual review completed on 09/30/2014. Clarified the indications and documentation requirements which are effective 01/15/2015. Formatting and typos corrected throughout. Updates National Coverage Policy and sources of information.	• Typographical Error • Other

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Associated Documents

Attachments N/A

Related Local Coverage Documents N/A

Related National Coverage Documents N/A

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