LCD L32562 - Flow Cytometry

Print

Contractor Information

Contractor Name:	Contractor Number(s):	Contractor Type:
Novitas Solutions, Inc.	12501, 12101, 12102, 12201, 12202, 12301, 12302, 12401, 12402, 12901, 12502	MAC Part A & B

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LCD Information

Document Information

LCD ID Number

L32562

LCD Title

Flow Cytometry

Contractor's Determination Number

L32562

AMA CPT/ADA CDT Copyright Statement

Primary Geographic Jurisdiction

Pennsylvania, Maryland, District of Columbia, New Jersey, Delaware

Oversight Region

Central Office

Original Determination Effective Date

For services performed on or after 11/15/2012

Original Determination Ending Date

N/A

Revision Effective Date

For services performed on or after N/A

Revision Ending Date

N/A

CMS National Coverage Policy

Title XVIII of the Social Security Act, Section 1862(a)(1)(A) states that no Medicare payment shall be made for items or services which are not reasonable and necessary for the diagnosis or treatment of illness or injury.

Title XVIII of the Social Security Act, Section 1862(a)(1)(D) 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.
Title XVIII of the Social Security Act, Section 1833(e) states that no payment shall be made to any provider for any claim that lacks the necessary information to process the claim.

This LCD supplements but does not replace, modify or supersede existing Medicare applicable National Coverage Determinations (NCDs) or payment policy rules and regulations for flow cytometry services. Federal statute and subsequent Medicare regulations regarding provision and payment for medical services are lengthy. They are not repeated in this LCD. Neither Medicare payment policy rules nor this LCD replace, modify or supersede applicable state statutes regarding medical practice or other health practice professions acts, definitions and/or scopes of practice. All providers who report services for Medicare payment must fully understand and follow all existing laws, regulations and rules for Medicare payment for flow cytometry services and must properly submit only valid claims for them. Please review and understand them and apply the medical necessity provisions in the policy within the context of the manual rules. Relevant CMS manual instructions and policies regarding flow cytometry services are found in the following Internet-Only Manuals (IOMs) published on the CMS website:
Medicare Benefit Policy Manual – Pub. 100-02.
Medicare National Coverage Determinations Manual – Pub. 100-03.
Correct Coding Initiative – Medicare Contractor Beneficiary and Provider Communications Manual – Pub. 100-09, Chapter 5.

Indications and Limitations of Coverage and/or Medical Necessity

Compliance with the provisions in this policy may be monitored and addressed through post payment data analysis and subsequent medical review audits.
Notice: It is not appropriate to bill Medicare for services that are not covered (as described by this entire LCD) as if they are covered.

Flow Cytometry is a highly complex process by which blood, body fluids, bone marrow and tissue can be examined. It provides important immunophenotypic and DNA cycle information, of both diagnostic and prognostic interest in hematopathology, cytopathology and general surgical pathology. The technique measures multiple characteristics (cell size, internal structure, antigens, DNA, ploidy and cell cycle analysis) of single cells in a moving fluid stream. Clinical analysis and interpretations are done by an experienced physician, usually a pathologist.

HIV Infection

The status of a Human Immunodeficiency Virus- (HIV) infected patient can be monitored by the analysis of the surface antigen CD4 (a T-cell receptor for HIV). This information can contribute to a prognosis as well as medical management for that individual (e.g., the need for AZT therapy or prophylaxis). Monitoring would be

considered appropriate no greater in frequency than 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 or therapy change, it may be necessary to perform the test at an increased frequency.)

Leukemia or Lymphoma

Leukemias and lymphomas may be analyzed in tissue, blood or marrow. Sometimes, 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 antibody panel for appropriate diagnosis and classification. In the great majority of cases, 20 antibody determinations are sufficient to address diagnostic and prognostic concerns. This process is usually necessary at the initial diagnostic phase, for separate hematologic malignancies or when tumor is present in several anatomic sites. After this initial diagnostic phase, flow cytometry may be indicated to determine response to therapy.

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 cells surface marker examined is CD3. This may require repeated analysis when symptoms are expressed for the above conditions by the transplant patient.

Carcinomas

DNA analysis of tumor for ploidy and percent-S-phase cells may be necessary for a few 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.

Primary Immunodeficiencies

Primary immunodeficiencies (e.g., Lymphocyte disorders, Phagocyte disorders, Monocyte/macrophage disorder) 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 failures. Initial evaluation for suspected primary immunodeficiencies includes physical exam, laboratory evaluation (e.g., CBC, platelet, 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.

It is expected that the initial evaluation will contain a higher number of antibody examinations than a subsequent antibody examination.

Compliance with the provisions in this policy is subject to monitoring by post payment data analysis and subsequent medical review.

Notice: This LCD imposes diagnosis limitations that support diagnosis to procedure code automated denials. However, services performed for any given diagnosis must meet all of the indications and limitations stated in this policy, the general requirements for medical necessity as stated in CMS payment policy manuals, any and all existing CMS national coverage determinations, and all Medicare payment rules.

As published in CMS IOM 100-08, Section 13.5.1, in order to be covered under Medicare, a service shall be reasonable and necessary. When appropriate, contractors shall describe the circumstances under which the proposed LCD for the service is considered reasonable and necessary under Section 1862(a)(1)(A). Contractors shall consider a service to be reasonable and necessary if the contractor determines that the service is:

1. Safe and effective.
2. Not experimental or investigational (exception: routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000, that meet the requirements of the Clinical Trials NCD are considered reasonable and necessary).
3. Appropriate, including the duration and frequency that is considered appropriate for the service, in terms of whether it is:
    - Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed bodymember.
    - Furnished in a setting appropriate to the patient's medical needs and condition.
    - Ordered and furnished by qualified personnel.
    - One that meets, but does not exceed, the patient's medical needs.
    - At least as beneficial as an existing and available medically appropriate alternative.

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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.

012x	Hospital Inpatient (Medicare Part B only)
013x	Hospital Outpatient
014x	Hospital - Laboratory Services Provided to Non-patients
018x	Hospital - Swing Beds

021x	Skilled Nursing - Inpatient (Including Medicare Part A)
071x	Clinic - Rural Health
072x	Clinic - Hospital Based or Independent Renal Dialysis Center
083x	Ambulatory Surgery Center
085x	Critical Access Hospital

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.

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

CPT/HCPCS Codes

Italicized and/or quoted material is excerpted from the American Medical Association, *Current Procedural Terminology (CPT)* codes.

88182	FLOW CYTOMETRY, CELL CYCLE OR DNA ANALYSIS
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

ICD-9 Codes that Support Medical Necessity

It is the provider's responsibility to select codes carried out to the highest level of specificity and selected from the ICD-9-CM code book appropriate to the year in which the service is rendered for the claim(s) submitted.

Medicare is establishing the following limited coverage for CPT/HCPCS codes *88184, 88185, 88187, 88188,* and *88189*:

042	HUMAN IMMUNODEFICIENCY VIRUS (HIV) DISEASE
079.51 - 079.53	HUMAN T-CELL LYMPHOTROPHIC VIRUS TYPE I [HTLV-I] - HUMAN IMMUNODEFICIENCY VIRUS TYPE 2 [HIV-2]
197.2	SECONDARY MALIGNANT NEOPLASM OF PLEURA
197.6	SECONDARY MALIGNANT NEOPLASM OF RETROPERITONEUM AND PERITONEUM
200.00 - 200.08	RETICULOSARCOMA UNSPECIFIED SITE - RETICULOSARCOMA INVOLVING LYMPH NODES OF MULTIPLE SITES
200.10 - 200.18	LYMPHOSARCOMA UNSPECIFIED SITE - LYMPHOSARCOMA INVOLVING LYMPH NODES OF MULTIPLE SITES
200.20 - 200.28	BURKITT'S TUMOR OR LYMPHOMA UNSPECIFIED SITE - BURKITT'S TUMOR OR LYMPHOMA INVOLVING LYMPH NODES OF MULTIPLE SITES
200.30 - 200.38	MARGINAL ZONE LYMPHOMA, UNSPECIFIED SITE, EXTRANODAL AND SOLID ORGAN SITES - MARGINAL ZONE LYMPHOMA, LYMPH NODES OF MULTIPLE SITES
200.40 - 200.48	MANTLE CELL LYMPHOMA, UNSPECIFIED SITE, EXTRANODAL AND SOLID ORGAN SITES - MANTLE CELL LYMPHOMA, LYMPH NODES OF MULTIPLE SITES
200.50 - 200.58	PRIMARY CENTRAL NERVOUS SYSTEM LYMPHOMA, UNSPECIFIED SITE, EXTRANODAL AND SOLID ORGAN SITES - PRIMARY CENTRAL NERVOUS SYSTEM LYMPHOMA, LYMPH NODES OF MULTIPLE SITES
200.60 - 200.68	ANAPLASTIC LARGE CELL LYMPHOMA, UNSPECIFIED SITE, EXTRANODAL AND SOLID ORGAN SITES - ANAPLASTIC LARGE CELL LYMPHOMA, LYMPH NODES OF MULTIPLE SITES
200.70 - 200.78	LARGE CELL LYMPHOMA, UNSPECIFIED SITE, EXTRANODAL AND SOLID ORGAN SITES - LARGE CELL LYMPHOMA, LYMPH NODES OF MULTIPLE SITES
200.80 - 200.88	OTHER NAMED VARIANTS OF LYMPHOSARCOMA AND RETICULOSARCOMA UNSPECIFIED SITE - OTHER NAMED

	VARIANTS OF LYMPHOSARCOMA AND RETICULOSARCOMA INVOLVING LYMPH NODES OF MULTIPLE SITES
201.00 - 201.08	HODGKIN'S PARAGRANULOMA UNSPECIFIED SITE - HODGKIN'S PARAGRANULOMA INVOLVING LYMPH NODES OF MULTIPLE SITES
201.10 - 201.18	HODGKIN'S GRANULOMA UNSPECIFIED SITE - HODGKIN'S GRANULOMA INVOLVING LYMPH NODES OF MULTIPLE SITES
201.20 - 201.28	HODGKIN'S SARCOMA UNSPECIFIED SITE - HODGKIN'S SARCOMA INVOLVING LYMPH NODES OF MULTIPLE SITES
201.40 - 201.48	HODGKIN'S DISEASE LYMPHOCYTIC-HISTIOCYTIC PREDOMINANCE UNSPECIFIED SITE - HODGKIN'S DISEASE LYMPHOCYTIC-HISTIOCYTIC PREDOMINANCE INVOLVING LYMPH NODES OF MULTIPLE SITES
201.50 - 201.58	HODGKIN'S DISEASE NODULAR SCLEROSIS UNSPECIFIED SITE - HODGKIN'S DISEASE NODULAR SCLEROSIS INVOLVING LYMPH NODES OF MULTIPLE SITES
201.60 - 201.68	HODGKIN'S DISEASE MIXED CELLULARITY UNSPECIFIED SITE - HODGKIN'S DISEASE MIXED CELLULARITY INVOLVING LYMPH NODES OF MULTIPLE SITES
201.70 - 201.78	HODGKIN'S DISEASE LYMPHOCYTIC DEPLETION UNSPECIFIED SITE - HODGKIN'S DISEASE LYMPHOCYTIC DEPLETION INVOLVING LYMPH NODES OF MULTIPLE SITES
201.90 - 201.98	HODGKIN'S DISEASE UNSPECIFIED TYPE UNSPECIFIED SITE - HODGKIN'S DISEASE UNSPECIFIED TYPE INVOLVING LYMPH NODES OF MULTIPLE SITES
202.00 - 202.08	NODULAR LYMPHOMA UNSPECIFIED SITE - NODULAR LYMPHOMA INVOLVING LYMPH NODES OF MULTIPLE SITES
202.10 - 202.18	MYCOSIS FUNGOIDES UNSPECIFIED SITE - MYCOSIS FUNGOIDES INVOLVING LYMPH NODES OF MULTIPLE SITES
202.20 - 202.28	SEZARY'S DISEASE UNSPECIFIED SITE - SEZARY'S DISEASE INVOLVING LYMPH NODES OF MULTIPLE SITES
202.30 - 202.38	MALIGNANT HISTIOCYTOSIS UNSPECIFIED SITE - MALIGNANT HISTIOCYTOSIS INVOLVING LYMPH NODES OF MULTIPLE SITES
202.40 - 202.48	LEUKEMIC RETICULOENDOTHELIOSIS UNSPECIFIED SITE - LEUKEMIC RETICULOENDOTHELIOSIS INVOLVING LYMPH NODES OF MULTIPLE SITES

202.50 - 202.58	LETTERER-SIWE DISEASE UNSPECIFIED SITE - LETTERER-SIWE DISEASE INVOLVING LYMPH NODES OF MULTIPLE SITES
202.60 - 202.68	MALIGNANT MAST CELL TUMORS UNSPECIFIED SITE - MALIGNANT MAST CELL TUMORS INVOLVING LYMPH NODES OF MULTIPLE SITES
202.70 - 202.78	PERIPHERAL T CELL LYMPHOMA, UNSPECIFIED SITE, EXTRANODAL AND SOLID ORGAN SITES - PERIPHERAL T CELL LYMPHOMA, LYMPH NODES OF MULTIPLE SITES
202.80 - 202.88	OTHER MALIGNANT LYMPHOMAS UNSPECIFIED SITE - OTHER MALIGNANT LYMPHOMAS INVOLVING LYMPH NODES OF MULTIPLE SITES
202.90 - 202.98	OTHER AND UNSPECIFIED MALIGNANT NEOPLASMS OF LYMPHOID AND HISTIOCYTIC TISSUE UNSPECIFIED SITE - OTHER AND UNSPECIFIED MALIGNANT NEOPLASMS OF LYMPHOID AND HISTIOCYTIC TISSUE INVOLVING LYMPH NODES OF MULTIPLE SITES
203.00	MULTIPLE MYELOMA, WITHOUT MENTION OF HAVING ACHIEVED REMISSION
203.02	MULTIPLE MYELOMA, IN RELAPSE
203.10 - 203.12	PLASMA CELL LEUKEMIA, WITHOUT MENTION OF HAVING ACHIEVED REMISSION - PLASMA CELL LEUKEMIA, IN RELAPSE
203.80 - 203.82	OTHER IMMUNOPROLIFERATIVE NEOPLASMS, WITHOUT MENTION OF HAVING ACHIEVED REMISSION - OTHER IMMUNOPROLIFERATIVE NEOPLASMS, IN RELAPSE
204.00 - 204.02	ACUTE LYMPHOID LEUKEMIA, WITHOUT MENTION OF HAVING ACHIEVED REMISSION - ACUTE LYMPHOID LEUKEMIA, IN RELAPSE
204.10 - 204.12	CHRONIC LYMPHOID LEUKEMIA, WITHOUT MENTION OF HAVING ACHIEVED REMISSION - CHRONIC LYMPHOID LEUKEMIA, IN RELAPSE
204.20 - 204.22	SUBACUTE LYMPHOID LEUKEMIA, WITHOUT MENTION OF HAVING ACHIEVED REMISSION - SUBACUTE LYMPHOID LEUKEMIA, IN RELAPSE
204.80 - 204.82	OTHER LYMPHOID LEUKEMIA, WITHOUT MENTION OF HAVING ACHIEVED REMISSION - OTHER LYMPHOID LEUKEMIA, IN RELAPSE

204.90 - 204.92	UNSPECIFIED LYMPHOID LEUKEMIA, WITHOUT MENTION OF HAVING ACHIEVED REMISSION - UNSPECIFIED LYMPHOID LEUKEMIA, IN RELAPSE
205.00 - 205.02	ACUTE MYELOID LEUKEMIA, WITHOUT MENTION OF HAVING ACHIEVED REMISSION - ACUTE MYELOID LEUKEMIA, IN RELAPSE
205.10 - 205.12	CHRONIC MYELOID LEUKEMIA, WITHOUT MENTION OF HAVING ACHIEVED REMISSION - CHRONIC MYELOID LEUKEMIA, IN RELAPSE
205.20 - 205.22	SUBACUTE MYELOID LEUKEMIA, WITHOUT MENTION OF HAVING ACHIEVED REMISSION - SUBACUTE MYELOID LEUKEMIA, IN RELAPSE
205.30 - 205.32	MYELOID SARCOMA, WITHOUT MENTION OF HAVING ACHIEVED REMISSION - MYELOID SARCOMA, IN RELAPSE
205.80 - 205.82	OTHER MYELOID LEUKEMIA, WITHOUT MENTION OF HAVING ACHIEVED REMISSION - OTHER MYELOID LEUKEMIA, IN RELAPSE
205.90 - 205.92	UNSPECIFIED MYELOID LEUKEMIA, WITHOUT MENTION OF HAVING ACHIEVED REMISSION - UNSPECIFIED MYELOID LEUKEMIA, IN RELAPSE
206.00 - 206.02	ACUTE MONOCYTIC LEUKEMIA, WITHOUT MENTION OF HAVING ACHIEVED REMISSION - ACUTE MONOCYTIC LEUKEMIA, IN RELAPSE
206.10 - 206.12	CHRONIC MONOCYTIC LEUKEMIA, WITHOUT MENTION OF HAVING ACHIEVED REMISSION - CHRONIC MONOCYTIC LEUKEMIA, IN RELAPSE
206.20 - 206.22	SUBACUTE MONOCYTIC LEUKEMIA, WITHOUT MENTION OF HAVING ACHIEVED REMISSION - SUBACUTE MONOCYTIC LEUKEMIA, IN RELAPSE
206.80 - 206.82	OTHER MONOCYTIC LEUKEMIA, WITHOUT MENTION OF HAVING ACHIEVED REMISSION - OTHER MONOCYTIC LEUKEMIA, IN RELAPSE
206.90 - 206.92	UNSPECIFIED MONOCYTIC LEUKEMIA, WITHOUT MENTION OF HAVING ACHIEVED REMISSION - UNSPECIFIED MONOCYTIC LEUKEMIA, IN RELAPSE
207.00 - 207.02	ACUTE ERYTHREMIA AND ERYTHROLEUKEMIA, WITHOUT MENTION OF HAVING ACHIEVED REMISSION - ACUTE ERYTHREMIA AND ERYTHROLEUKEMIA, IN RELAPSE

207.10 - 207.12	CHRONIC ERYTHREMIA, WITHOUT MENTION OF HAVING ACHIEVED REMISSION - CHRONIC ERYTHREMIA, IN RELAPSE
207.20 - 207.22	MEGAKARYOCYTIC LEUKEMIA, WITHOUT MENTION OF HAVING ACHIEVED REMISSION - MEGAKARYOCYTIC LEUKEMIA, IN RELAPSE
207.80 - 207.82	OTHER SPECIFIED LEUKEMIA, WITHOUT MENTION OF HAVING ACHIEVED REMISSION - OTHER SPECIFIED LEUKEMIA, IN RELAPSE
208.00 - 208.02	ACUTE LEUKEMIA OF UNSPECIFIED CELL TYPE, WITHOUT MENTION OF HAVING ACHIEVED REMISSION - ACUTE LEUKEMIA OF UNSPECIFIED CELL TYPE, IN RELAPSE
208.10 - 208.12	CHRONIC LEUKEMIA OF UNSPECIFIED CELL TYPE, WITHOUT MENTION OF HAVING ACHIEVED REMISSION - CHRONIC LEUKEMIA OF UNSPECIFIED CELL TYPE, IN RELAPSE
208.20 - 208.22	SUBACUTE LEUKEMIA OF UNSPECIFIED CELL TYPE, WITHOUT MENTION OF HAVING ACHIEVED REMISSION - SUBACUTE LEUKEMIA OF UNSPECIFIED CELL TYPE, IN RELAPSE
208.80 - 208.82	OTHER LEUKEMIA OF UNSPECIFIED CELL TYPE, WITHOUT MENTION OF HAVING ACHIEVED REMISSION - OTHER LEUKEMIA OF UNSPECIFIED CELL TYPE, IN RELAPSE
208.90 - 208.92	UNSPECIFIED LEUKEMIA, WITHOUT MENTION OF HAVING ACHIEVED REMISSION - UNSPECIFIED LEUKEMIA, IN RELAPSE
238.71 - 238.77	ESSENTIAL THROMBOCYTHEMIA - POST-TRANSPLANT LYMPHOPROLIFERATIVE DISORDER (PTLD)
238.79	OTHER LYMPHATIC AND HEMATOPOIETIC TISSUES
273.1 - 273.3	MONOCLONAL PARAPROTEINEMIA - MACROGLOBULINEMIA
273.8 - 273.9	OTHER DISORDERS OF PLASMA PROTEIN METABOLISM - UNSPECIFIED DISORDER OF PLASMA PROTEIN METABOLISM
279.00 - 279.06	HYPOGAMMAGLOBULINEMIA UNSPECIFIED - COMMON VARIABLE IMMUNODEFICIENCY
279.09	OTHER DEFICIENCY OF HUMORAL IMMUNITY
279.10 - 279.13	IMMUNODEFICIENCY WITH PREDOMINANT T-CELL DEFECT UNSPECIFIED - NEZELOF'S SYNDROME
279.19	OTHER DEFICIENCY OF CELL-MEDIATED IMMUNITY
279.2 - 279.3	COMBINED IMMUNITY DEFICIENCY - UNSPECIFIED

	IMMUNITY DEFICIENCY
279.41	AUTOIMMUNE LYMPHOPROLIFERATIVE SYNDROME
279.49	AUTOIMMUNE DISEASE, NOT ELSEWHERE CLASSIFIED
279.8 - 279.9	OTHER SPECIFIED DISORDERS INVOLVING THE IMMUNE MECHANISM - UNSPECIFIED DISORDER OF IMMUNE MECHANISM
282.7	OTHER HEMOGLOBINOPATHIES
283.2	HEMOGLOBINURIA DUE TO HEMOLYSIS FROM EXTERNAL CAUSES
284.01	CONSTITUTIONAL RED BLOOD CELL APLASIA
284.09	OTHER CONSTITUTIONAL APLASTIC ANEMIA
284.11 - 284.12	ANTINEOPLASTIC CHEMOTHERAPY INDUCED PANCYTOPENIA - OTHER DRUG INDUCED PANCYTOPENIA
284.19	OTHER PANCYTOPENIA
284.2	MYELOPHTHISIS
284.81	RED CELL APLASIA (ACQUIRED) (ADULT) (WITH THYMOMA)
284.89	OTHER SPECIFIED APLASTIC ANEMIAS
284.9	APLASTIC ANEMIA UNSPECIFIED
285.0	SIDEROBLASTIC ANEMIA
285.22	ANEMIA IN NEOPLASTIC DISEASE
285.8 - 285.9	OTHER SPECIFIED ANEMIAS - ANEMIA UNSPECIFIED
287.30 - 287.33	PRIMARY THROMBOCYTOPENIA,UNSPECIFIED - CONGENITAL AND HEREDITARY THROMBOCYTOPENIC PURPURA
287.39	OTHER PRIMARY THROMBOCYTOPENIA
287.5	THROMBOCYTOPENIA UNSPECIFIED
288.00 - 288.04	NEUTROPENIA, UNSPECIFIED - NEUTROPENIA DUE TO INFECTION
288.09	OTHER NEUTROPENIA
288.1 - 288.4	FUNCTIONAL DISORDERS OF POLYMORPHONUCLEAR NEUTROPHILS - HEMOPHAGOCYTIC SYNDROMES

288.50 - 288.51	LEUKOCYTOPENIA, UNSPECIFIED - LYMPHOCYTOPENIA
288.59	OTHER DECREASED WHITE BLOOD CELL COUNT
288.60 - 288.65	LEUKOCYTOSIS, UNSPECIFIED - BASOPHILIA
288.69	OTHER ELEVATED WHITE BLOOD CELL COUNT
288.8 - 288.9	OTHER SPECIFIED DISEASE OF WHITE BLOOD CELLS - UNSPECIFIED DISEASE OF WHITE BLOOD CELLS
289.4	HYPERSPLENISM
289.50 - 289.53	DISEASE OF SPLEEN UNSPECIFIED - NEUTROPENIC SPLENOMEGALY
289.59	OTHER DISEASES OF SPLEEN
289.83	MYELOFIBROSIS
289.9	UNSPECIFIED DISEASES OF BLOOD AND BLOOD-FORMING ORGANS
452	PORTAL VEIN THROMBOSIS
453.9	EMBOLISM AND THROMBOSIS OF UNSPECIFIED SITE
785.6	ENLARGEMENT OF LYMPH NODES
789.2	SPLENOMEGALY
791.0	PROTEINURIA
795.4	OTHER NONSPECIFIC ABNORMAL HISTOLOGICAL FINDINGS
996.80 - 996.89	COMPLICATIONS OF UNSPECIFIED TRANSPLANTED ORGAN - COMPLICATIONS OF OTHER SPECIFIED TRANSPLANTED ORGAN
V08	ASYMPTOMATIC HUMAN IMMUNODEFICIENCY VIRUS (HIV) INFECTION STATUS
V10.60 - V10.63	PERSONAL HISTORY OF UNSPECIFIED LEUKEMIA - PERSONAL HISTORY OF MONOCYTIC LEUKEMIA
V10.69	PERSONAL HISTORY OF OTHER LEUKEMIA
V10.91	PERSONAL HISTORY OF MALIGNANT NEUROENDOCRINE TUMOR
V42.0 - V42.7	KIDNEY REPLACED BY TRANSPLANT - LIVER REPLACED BY TRANSPLANT

V42.81 - V42.84	BONE MARROW REPLACED BY TRANSPLANT - ORGAN OR TISSUE REPLACED BY TRANSPLANT INTESTINES
V42.89	OTHER SPECIFIED ORGAN OR TISSUE REPLACED BY TRANSPLANT
V42.9	UNSPECIFIED ORGAN OR TISSUE REPLACED BY TRANSPLANT

Medicare is establishing the following limited coverage for CPT/HCPCS code *88182*:

150.0 - 150.5	MALIGNANT NEOPLASM OF CERVICAL ESOPHAGUS - MALIGNANT NEOPLASM OF LOWER THIRD OF ESOPHAGUS
150.8 - 150.9	MALIGNANT NEOPLASM OF OTHER SPECIFIED PART OF ESOPHAGUS - MALIGNANT NEOPLASM OF ESOPHAGUS UNSPECIFIED SITE
151.0 - 151.6	MALIGNANT NEOPLASM OF CARDIA - MALIGNANT NEOPLASM OF GREATER CURVATURE OF STOMACH UNSPECIFIED
151.8 - 151.9	MALIGNANT NEOPLASM OF OTHER SPECIFIED SITES OF STOMACH - MALIGNANT NEOPLASM OF STOMACH UNSPECIFIED SITE
153.0 - 153.9	MALIGNANT NEOPLASM OF HEPATIC FLEXURE - MALIGNANT NEOPLASM OF COLON UNSPECIFIED SITE
154.0	MALIGNANT NEOPLASM OF RECTOSIGMOID JUNCTION
154.1	MALIGNANT NEOPLASM OF RECTUM
174.0 - 174.6	MALIGNANT NEOPLASM OF NIPPLE AND AREOLA OF FEMALE BREAST - MALIGNANT NEOPLASM OF AXILLARY TAIL OF FEMALE BREAST
174.8 - 174.9	MALIGNANT NEOPLASM OF OTHER SPECIFIED SITES OF FEMALE BREAST - MALIGNANT NEOPLASM OF BREAST (FEMALE) UNSPECIFIED SITE
175.0	MALIGNANT NEOPLASM OF NIPPLE AND AREOLA OF MALE BREAST
175.9	MALIGNANT NEOPLASM OF OTHER AND UNSPECIFIED SITES OF MALE BREAST
183.0	MALIGNANT NEOPLASM OF OVARY
183.8	MALIGNANT NEOPLASM OF OTHER SPECIFIED SITES OF

	UTERINE ADNEXA
185	MALIGNANT NEOPLASM OF PROSTATE
188.0	MALIGNANT NEOPLASM OF TRIGONE OF URINARY BLADDER
188.1 - 188.9	MALIGNANT NEOPLASM OF DOME OF URINARY BLADDER - MALIGNANT NEOPLASM OF BLADDER PART UNSPECIFIED
193	MALIGNANT NEOPLASM OF THYROID GLAND
194.0	MALIGNANT NEOPLASM OF ADRENAL GLAND
198.81	SECONDARY MALIGNANT NEOPLASM OF BREAST
227.0	BENIGN NEOPLASM OF ADRENAL GLAND
233.0	CARCINOMA IN SITU OF BREAST
259.2	CARCINOID SYNDROME

Diagnoses that Support Medical Necessity

Conditions that are listed in the "ICD-9 Codes that Support Medical Necessity" section of this policy.

ICD-9 Codes that DO NOT Support Medical Necessity

All those not listed under the "ICD-9 Codes that Support Medical Necessity" section of this policy.

ICD-9 Codes that DO NOT Support Medical Necessity Asterisk Explanation

Diagnoses that DO NOT Support Medical Necessity

Conditions that are not listed in the "ICD-9 Codes that Support Medical Necessity" section of this policy.

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Other Information

Documentation Requirements

1. All documentation must be maintained in the patient's medical record and available to the contractor upon request.
2. Every page of the record must be legible and include appropriate patient identification information (e.g., complete name, dates of service(s)). The documentation must include the legible signature of the physician or non-physician practitioner responsible for and providing the care to the patient.
3. The submitted medical record must support the use of the selected ICD-9-CM code(s). The submitted CPT/HCPCS code must describe the service performed.
4. The medical record documentation must support the medical necessity of the services as directed in this policy.

5. Per the Utilization Guidelines below, the provider must have documentation to justify why the initial, presumptive flow-cytometry based diagnosis requires additional cell surface marker information to obtain further clarification and refinement of this working diagnosis. Therefore, this documentation must concisely summarize the reason for the need for additional numbers and types of additional cell surface markers in order to ensure a high-quality final diagnosis, based on flow cytometry.

Appendices

N/A

Utilization Guidelines

In accordance with CMS Ruling 95-1 (V), utilization of these services should be consistent with locally acceptable standards of practice.

Routinely performing more than 20 analyses (or units of *88185*) per specimen is not expected by Medicare.
Notice: This LCD imposes utilization guideline limitations. Despite Medicare's allowing up to these maximum number of units of service, each patient's condition and response to treatment must medically warrant the number of services reported for payment. Medicare requires the medical necessity for each service reported to be clearly demonstrated in the patient's medical record. Medicare expects that patients will not routinely require the maximum allowable number of services. In specific, many "routine" (e.g., anemia of unknown etiology) evaluations will be expected to require a relatively few number of cell surface markers, which, in the absence of more severe pathology, should not typically require further flow cytometry analysis. Conversely, for the appropriate diagnosis of some newly-discovered neoplasms (e.g., leukemias), there may be special classification challenges where a progression of cell surface marker evaluations becomes medically necessary for that difficult-to-diagnose neoplasm. In other words, the billing of *88185* must reflect the thoughtful, step-wise (i.e., algorithmic) approach to evaluating specimens in marked contradistinction to any use of standard "global-type" cell surface marker testing panels, which do not carefully adhere to this principle of thoughtful, sequential diagnostic reasoning.

Sources of Information and Basis for Decision

Contractor is not responsible for the continued viability of websites listed.
Other Contractor Local Coverage Determinations:

"Flow Cytometry", TrailBlazer LCD, (00400) L17534, (00900) L16605.

"Flow Cytometry", Noridian Administrative Services, LLC LCD, (CO) L23806.
Contractor Medical Directors

Advisory Committee Meeting Notes

This policy does not reflect the sole opinion of the contractor or Contractor Medical Directors. Although the final decision rests with the contractor, this policy was developed in cooperation with advisory groups, which includes representatives from the appropriate specialty (ies).
CAC Distribution: 05/15/2012

Start Date of Comment Period

05/15/2012

End Date of Comment Period:

07/05/2012

Start Date of Notice Period

09/27/2012

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Revision History

Revision History Number

L32562

Revision History Explanation

Date	Policy #	Description
09/27/2012	L32562	Final LCD posted for notice and will become effective for dates of service on and after 11/15/2012.
05/15/2012	DL32562	Draft LCD posted for comment.

Reason for Change

Coverage Change (actual change in medical parameters)

Related Documents

This LCD has no related documents.

LCD Attachments

There are no attachments for this LCD.