Flow Cytometry

CPT: 88182, 88184, 88185, 88187, 88188, 88189

CMS Policy for Delaware, Maryland, New Jersey, Pennsylvania, Virginia (Suburbs), and Washington, D.C.

Local policies are determined by the performing test location. This is determined by the state in which your performing laboratory resides and where your testing is commonly performed.

Medically Supportive ICD Codes are listed on subsequent page(s) of this document.

Coverage Indications, Limitations, and/or Medical Necessity

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. When billing for non-covered services, use the appropriate modifier. Compliance with the provisions in this policy may be monitored and addressed through post payment data analysis and Subsequent medical review audits.

History/Background and/or General Information

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 hemopathology, 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.

Covered Indications

1. 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.)

2. 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.

3. 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.

4. 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.

5. 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.

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Limitations

For frequency limitations please refer to the Utilization Guidelines section below.

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, Chapter 13, 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:

- Safe and effective;
- 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);
- 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 body member;
  - 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.

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 per specimen is not expected by Medicare.

Notice: This LCD imposes utilization guideline limitations. Despite Medicare's allowing up to these maximums, 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.

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There is a frequency associated with this test. Please refer to the Limitations or Utilization Guidelines section on previous page(s).

The ICD10 codes listed below are the top diagnosis codes currently utilized by ordering physicians for the limited coverage test highlighted above that are also listed as medically supportive under Medicare's limited coverage policy. **If you are ordering this test for diagnostic reasons that are not covered under Medicare policy, an Advance Beneficiary Notice form is required.**
Note—Bolded diagnoses below have the highest utilization

Code	Description
C91.10	**Chronic lymphocytic leukemia of B-cell type not having achieved remission**
C78.6	Secondary malignant neoplasm of retroperitoneum and peritoneum
C83.38	Diffuse large B-cell lymphoma, lymph nodes of multiple sites
C85.89	Other specified types of non-Hodgkin lymphoma, extranodal and solid organ sites
C85.99	Non-Hodgkin lymphoma, unspecified, extranodal and solid organ sites
D47.1	Chronic myeloproliferative disease
D64.9	**Anemia, unspecified**
D69.6	Thrombocytopenia, unspecified
D72.810	Lymphocytopenia
D72.821	Monocytosis (symptomatic)
D72.828	Other elevated white blood cell count
R59.9	Enlarged lymph nodes, unspecified

Visit **QuestDiagnostics.com/MLCP** to view current limited coverage tests, reference guides, and policy information.
To view the complete policy and the full list of medically supportive codes, please refer to the CMS website reference www.cms.gov ▶

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