Reimbursement Policy

Flow Cytometry

I. Policy Description

Flow Cytometry is a technique for live cell analysis that measures optical light scattering features to determine physical characteristics.[1] This instrument is beneficial for calculating the number of cells in a biologic sample, as well as for measuring cellular properties, such as size, shape, viability, and granularity.[2] Flow cytometry may also be used for diagnostic and prognostic purposes when monitoring certain diseases, and for identifying the presence of specific biomarkers.

Flow cytometry-derived DNA content can be used for cell cycle analysis to estimate the percentages of a cell population in the various phases of the cell cycle; it can also be used with other reagents to analyze only the S phase. An S-phase fraction (SPF) is an assessment of how many cells are actively synthesizing DNA.[3] It is used as a measure of cell proliferation, particularly for cancer.[4] A high SPF value is indicative of rapid cancer growth.[5]

For guidance on flow cytometry in minimal residual disease (MRD), please see AHS-M2175-Minimal Residual Disease (MRD).

II. Indications and/or Limitations of Coverage

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request. Specifications pertaining to Medicare and Medicaid can be found in the "Applicable State and Federal Regulations" section of this policy document.

1) Flow cytometry immunophenotyping of cell surface markers **MEETS COVERAGE CRITERIA** for any of the following conditions:

   a) For individuals with cytopenias, lymphomas, leukemia, myeloproliferative and lymphoproliferative disorders, or myelodysplastic syndrome.

   b) For B-cell monitoring for immunosuppressive disorders.

   c) For T-cell monitoring for HIV infection and AIDS.

   d) For individuals with mast cell neoplasms.

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e) For individuals with paroxysmal nocturnal hemoglobinuria.

f) For preoperative or post-operative monitoring of individuals who will undergo or who have undergone organ transplantation.

g) For individuals with plasma cell disorders.

h) For individuals with primary immunodeficiencies (PIDs).

i) For individuals with primary platelet disorders (non-neoplastic).

j) For individuals with red cell and white cell disorders (non-neoplastic).

2) The following reimbursement limitations will apply for flow cytometry:

a) For flow cytometric immunophenotyping for the assessment of potential hematolymphoid neoplasia, use codes 88184-88189.

b) Code 88184 should be used for the first marker, per specimen, and is reimbursable up to a maximum of two units per date of service.

c) Code 88185 should be used for each additional marker and is reimbursable up to a maximum of 35 units, per date of service.

d) In patients with a neoplasm with an established immunophenotype, subsequent tests for that neoplasm should be limited to diagnostically relevant markers.

e) Codes 88187, 88188, and 88189 should not be used together for a single specimen in any combination.

f) Codes 88187, 88188, and 88189 are reimbursed at one unit per specimen, up to two specimens, per date of service.

g) Codes 88187-88189 should not be used in conjunction with codes 86355, 86356, 86357, 86359, 86360, 86361, 86367.

h) Use codes 86355, 86357, 86359, 86360, 86361, or 86367 for cell enumeration. These codes are reimbursable as single units only.

The following does not meet coverage criteria due to a lack of available published scientific literature confirming that the test(s) is/are required and beneficial for the diagnosis and treatment of an individual's illness.

3) Measurement of flow cytometry-derived DNA content (DNA Index) or cell proliferative activity (S-phase fraction or % S-phase) for prognostic or therapeutic purposes in the routine clinical management of cancers **DOES NOT MEET COVERAGE CRITERIA**.

III. Applicable State and Federal Regulations

DISCLAIMER: If there is a conflict between this policy and any relevant, applicable government policy for a particular member [e.g., Local Coverage Determinations (LCDs) or National Coverage Determinations (NCDs) for Medicare and/or state coverage for Medicaid], then the government policy will be used to make the determination. For the most up-to-date Medicare policies and coverage, please visit the Medicare search website https://www.cms.gov/medicare-coverage-database/search.aspx. For the most up-to-date Medicaid policies and coverage, visit the applicable state Medicaid website.

Food and Drug Administration (FDA)

Many labs have developed specific tests that they must validate and perform in house. These laboratory-developed tests (LDTs) are regulated by the Centers for Medicare and Medicaid (CMS) as high-complexity tests under the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88). LDTs are not approved or cleared by the U. S. Food and Drug Administration; however, FDA clearance or approval is not currently required for clinical use.

IV. Applicable CPT/HCPCS Procedure Codes

CPT	Code Description
86355	B cells, total count
86356	Mononuclear cell antigen, quantitative (eg, flow cytometry), not otherwise specified, each antigen
86357	Natural killer (NK) cells, total count
86359	T cells; total count
86360	T cells; absolute CD4 and CD8 count, including ratio
86361	T cells; absolute CD4 count
86367	Stem cells (ie, CD34), total count
88182	Flow cytometry, cell cycle or DNA analysis

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CPT	Code Description
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

Procedure codes appearing in Medical Policy documents are included only as a general reference tool for each policy. They may not be all-inclusive.

V. Evidence-based Scientific References

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