Flow Cytometry

Policy MP-044

Origination Date: 07/22/2020

Reviewed/Revised Date: 06/21/2023

Next Review Date: 06/21/2024

Current Effective Date: 06/21/2023

Disclaimer:

1. Policies are subject to change in accordance with State and Federal notice requirements.
2. Policies outline coverage determinations for U of U Health Plans Commercial and Healthy U (Medicaid) plans. Refer to the "Policy" section for more information.
3. Services requiring prior-authorization may not be covered, if prior-authorization is not obtained.
4. This Medical Policy does not guarantee coverage or payment of the service. The service must be a benefit in the member's plan and the member must be eligible for coverage at the time of service. Additional payment guidelines may be applied that are not included in this policy.

Description:

Flow cytometry is a laboratory test used to evaluate cells from blood, bone marrow, body fluids such as cerebrospinal fluid (CSF), or tumor tissue which is treated with special antibodies. Each antibody sticks only to certain types of cells that have the antigens that fit with it. The cells are then passed in front of a laser beam. If the cells now have those antibodies, the laser will make them give off light that's then measured and analyzed by a computer.

It can also be used to measure the amount of DNA in cancer cells (called ploidy). Instead of using antibodies to detect protein antigens, cells can be treated with special dyes that react with DNA. If there's a normal amount of DNA, the cells are said to be diploid, an abnormal amount of cells are aneuploid. Most aneuploid cancers of (but not all) organs tend to grow and spread faster than diploid ones.

Another use of flow cytometry is to measure the S-phase fraction, which is the percentage of cells in a sample that are in a certain stage of cell division called the synthesis or S-phase. The more cells that are in the S-phase, the faster the tissue is growing and the more aggressive the cancer is likely to be.

Flow cytometry is beneficial for the diagnosis, prognosis and monitoring of hematopoietic cancers, including lymphomas and leukemia, plasma cell neoplasms, myelodysplastic syndromes, myeloproliferative neoplasms, and certain anemias, human immunodeficiency virus/acquired immunodeficiency syndrome (HIV/AIDS), primary immunodeficiency disorders, molar pregnancies, paroxysmal hemoglobinuria and monitoring after transplantation. It is also

used to detect the presence of minimal residual disease and antigens used as therapeutic drug targets for cancer therapy.

Policy Statement and Criteria

1. Commercial Plans

U of U Health Plans considers flow cytometry medically necessary for the following assessment of these conditions:

A. Cytopenias, lymphomas, acute leukemia and lymphoproliferative disorders or;

B. B-cell monitoring for immunosuppressive disorders;

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

D. Hypercellular Hematolymphoid Disorders

E. Mast cell neoplasms

F. Minimal Residual Disease (MRD)

G. Molar pregnancy

H. Multiple Myeloma

I. Myelodysplastic syndrome & Chronic Myeloproliferative Disorders (CMPD)

J. Paroxysmal nocturnal hemoglobinuria

K. Plasma cell disorders

L. Post-operative monitoring of members who have undergone organ transplantation

M. Primary Immunodeficiencies (PIDs), and PIDs involving T, NK

N. Primary Platelet Disorders, Non-neoplastic

O. Red Cell and White Cell Disorders, Non-neoplastic

P. T-cell monitoring for HIV infection and AIDS

Limitations: Since flow cytometry immunophenotypes for most common lymphomas and leukemias are well characterized, U of U Health Plans does NOT consider it “reasonable and necessary” to perform more than 24 markers in a panel. Therefore, for any indication the quantity limit is 24 units total of 88184-88189

When atypical or unusual FCM (Fuzzy C-Mean) results are obtained, the selective addition of more markers may be indicated. The flow cytometry report must document the specific indication for each marker over the 24 marker limit. The FCM report must document the specific indication for each marker over the 24-marker limit. FCM reports without clear justification for each marker over 24 will be denied.

A Flow cytometry performed more than every 3 months to monitor stable HIV infection is not considered reasonable or necessary. More frequent studies may be indicated if a patient develops drug resistance and needs to be treated with another antiviral(s).

U of U Health Plans does NOT cover flow cytometry in any other circumstances as it is considered investigational because its effectiveness has not been established.

2. **Medicaid Plans**
   Coverage is determined by the State of Utah Medicaid program; if Utah State Medicaid has no published coverage position and InterQual criteria are not available, the U of U Health Plans Commercial criteria will apply. For the most up-to-date Medicaid policies and coverage, please visit their website at: https://medicaid.utah.gov/utah-medicaid-official-publications/ or the Utah Medicaid code Look-Up tool

   CPT/HCPCS codes covered by Utah State Medicaid may still require further evaluation to determine medical necessity for coverage.

Clinical Rationale

In 2007 two studies (Davis et.al. and Wood et al.) published findings from the Bethesda International Consensus Recommendations, on the clinical use of flow cytometry (FC) of hematolymphoid neoplasia along with optimal reagents and reporting for the flow cytometric diagnosis of hematopoietic neoplasia. According to the panel, flow cytometry demonstrated usefulness for the evaluation of cytopenias, elevated leukocyte count, observation of atypical cells or blasts and evaluation of body fluids, plasmacytosis or monoclonal gammopathy, organomegaly and tissue masses, and certain patient monitoring indications. However, they did not indicate it for mature neutrophilia, polyclonal hypergammaglobulinemia, polycythemia, thrombocytosis, and basophilia because “they are usually not associated with hematolymphoid malignancy or associated with hematolymphoid neoplasms that are not detectable by” flow cytometry.

As for the reagents of the initial evaluation panel, Bethesda recommendations suggest that the selections should be based on specimen type (peripheral blood, bone marrow, tissue, etc.), clinical information and cell morphology studies. They also identified initial panels for specific indications that range from 4 to a maximum of 12 reagents.

In 2007 Davis et al., reported on the international consensus recommendations for medical indications, regarding the use of flow cytometry for hematologic neoplasia. They support use of FC for the following clinical indications; cytopenias, elevated leukocyte count, identification of blasts in the marrow or peripheral blood, plasmacytosis or monoclonal gammopathy, tissue-based lymphoid neoplasia, lymph adenopathy, staging disease to document the extent of involvement, detecting potential therapeutic targets, assessment of response to therapy (e.g., minimal residual disease), documentation of progression or relapse, diagnosis of related disease (e.g., treatment-related or coincidental), documentation of disease acceleration, prognostication. The report concluded that the role of FC is important for selection or development of personalized treatment and encouragement for the development of new strategies. However, the biological analyses of neoplasms exceed personalized

treatment options, thus, further clinical trials and periodic reviews are needed to assess the medical indications of FC to keep up with scientific and clinical advancements.

A 2008 study (Ludovini et al) described the impact on the outcome in non-small cell lung cancer (NSCLC) by assessing the relationship between a panel of biological markers (p53, Bcl-2, HER-2, Ki67, DNA ploidy and S-phase fraction) and clinical-pathological parameters. Tumor tissue specimens were collected from 136 consecutive patients with NSCLC following surgical resection. An immunocytochemical (ICC) technique and flow cytometric DNA analysis were used to evaluate p53, Bcl-2, HER-2 and Ki67. Positivity of p53, Bcl-2, HER-2 and Ki67 was detected in 51.4%, 27.9%, 25.0% and 55.8% of the samples, respectively; 82.9% of the cases revealed aneuploid DNA histograms and 56.7% presented an S-phase fraction of more than 12%. At univariate analysis, high Ki67 proved to be the only marker associated with disease-free survival ($p = 0.047$). After adjusting for stage, none of the examined ICC markers emerged as an independent factor for disease-free and overall survival; only pathological stage was identified as an independent prognostic factor for disease-free survival ($p = 0.0001$) and overall survival ($p = 0.0001$). In conclusion, the findings did not support a relevant prognostic role of ICC markers in NSCLC. Furthermore, the National Comprehensive Cancer Network's practice guidelines for "Non-Small Cell Lung Cancer" (Version 3.2023) do not mention flow cytometry as a management tool.

A 2013 retrospective correlational study (Dayal et al.) reported results on the application of multiparameter flow cytometry and examined the clinical and biomarker associations in 201 formalin-fixed, paraffin-embedded previously banked breast cancer specimens. Tumors were grouped into 4 categories based on the DNA index of the tumor cell population. Univariate statistical analysis demonstrated significant association with tumor category and prognosis in three of four tumor groups; however an independent association between tumor DNA content and overall survival was not confirmed by multivariate analysis. The authors found that the alterations in the DNA content show potential to further understandings on the mechanisms underlying clinically significant biomarker changes in breast cancer. However, more studies are needed before flow cytometry may be treated as a standard clinical practice for the detection of breast cancer ploidy or DNA index.

Flow cytometry is used in monitoring lymphocyte populations, (e.g., T-cells, natural killer [NK] cells), especially in individuals with a primary immunodeficiency disorder or HIV/AIDs by tracking the number and ratio of antigen-specific T cells (CD4, CD8). Flow cytometry is a critical tool and routine procedure for CD4 T-cell counting in peripheral blood of HIV1 patients for the management of HIV disease. Specifically, for guiding treatment against strategic infections, CD4 T-cell counting is used to measure the degree of immune deficiency, eligibility of HIV1 patients for antiretroviral treatment and to monitor immune restoration in an individual receiving antiretroviral therapy. CD4 T-cell counting is a valuable tool for directing treatment against opportunistic infections (Kestens et. al., 2017). Another clinical use of flow cytometry (Antin et al., 2001) is in understanding the biologic events that occur after transplantation, for instance, being able to detect lineage specific chimerism, graft rejection following transplantation, and to monitor the efficacy of immunosuppressive therapy.

And finally a 2019 study by Ye et al., examined flow cytometry and cytomorphology capabilities in detecting neuroblastoma cells in 21 patients with suspected neuroblastoma metastasis. Bone marrow and effusion specimens were tested by flow cytometry and cytomorphology. A total of 16 effusion (76.2%) and 9 BM (42.9%) specimens were classified by flow cytometry as positive for malignancy. Cytomorphology revealed 12 (57.1%) and 9 (42.9%) positive effusion and bone marrow specimens, respectively. Cytomorphology detected 3 effusions not detected by flow cytometry. There was no significant differences between flow cytometry and cytomorphology in the detection of neuroblastoma cells in effusions ($p = 0.344$). The authors concluded that flow cytometry may be used in conjunction

with cytomorphology, however, additional studies are needed to establish improved health outcomes in the use of flow cytometry compared to current cytomorphology methods.

The National Comprehensive Cancer Network (NCCN®) Biomarkers Compendium® (2020): The Compendium notes that flow cytometry may be used to assess the following hematologic lymphoid cancers:

- Acute Lymphoblastic Leukemia
- Aids-Related Kaposi Sarcoma
- Castleman's Disease
- Chronic Lymphocytic Leukemia
- Leukemia
- Chronic Myelogenous Leukemia
- Lymphomas
- Hairy Cell Leukemia
- Myeloproliferative Neoplasms
- Myelodysplastic Syndromes (MDS)
- Multiple Myeloma
- Post-Transplant Lymphoproliferative Disorders
- Systematic Light Chain Amyloidosis
- Systemic Mastocytosis
- Waldenstrom's Macroglobinemia

Flow cytometry is not mentioned in the Compendium as a laboratory method used for the diagnosis or management of solid tumors, including any of the following: bladder, brain, breast, colon, endometrium, gastric, kidney, lung, neuroblastoma, ovary, prostate or rectum.

Applicable Coding

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

HCPCS Codes

No applicable codes

ICD-10 Codes

A02.1	Salmonella sepsis	**A07.3**	Isosporiasis
A07.2	Cryptosporidiosis	**A15.0-A19.9**	Tuberculosis

A31.0	Pulmonary mycobacterial infection
A31.2	Disseminated mycobacterium avium-intracellulare complex (DMAC)
A31.8	Other mycobacterial infections
A81.2	Progressive multifocal leukoencephalopathy
B00.0	Eczema herpeticum
B00.1	Herpes viral vesicular dermatitis
B00.2	Herpes viral gingivostomatitis and pharyngotonsillitis
B00.89	Other herpes viral infection
B20	Human immunodeficiency virus [HIV] disease
B25.0-B25.9	Cytomegaloviral disease
B37.1	Pulmonary candidiasis
B37.81	Candidal esophagitis
B37.89	Other sites of candidiasis
B38.9	Coccidioidomycosis, unspecified
B39.2	Pulmonary histoplasmosis capsulati, unspecified
B39.3	Disseminated histoplasmosis capsulati
B39.4	Pneumocystosis
B45.0-B45.9	Cryptococcosis
B58.2	Toxoplasma meningoencephalitis
B59	Pneumocystosis
B97.33	Human T-cell lymphotrophic virus, type I [HTLV-I] as the cause of diseases classified elsewhere
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
C46.0-C46.9	Kaposi's sarcoma
C53.0-C53.9	Malignant neoplasm of cervix uteri
C58	Malignant neoplasm of placenta
C81.0	Nodular lymphocyte predominant Hodgkin lymphoma
C81.00 - C86.6	Malignant neoplasm of lymphoid, hematopoietic and related tissue
C81.00-C81.99	Hodgkin lymphoma
C82.0	Follicular lymphoma grade I
C82.00-C82.99	Follicular lymphoma
C83.00-C83.99	Non-follicular lymphoma
C84.00-C84.99	Mature T/NK-cell lymphomas
C84.4	Peripheral T-cell lymphoma, not classified
C84.6	Anaplastic large cell lymphoma, ALK-positive
C84.7	Anaplastic large cell lymphoma, ALK-negative
C84.9	Mature T/NK-cell lymphomas, unspecified
C84.A-C84.A9	Cutaneous T-cell lymphoma, unspecified
C84.Z0-C84.Z9	Other mature T/NK-cell lymphomas
C85.10-C85.19	Unspecified B-cell lymphoma
C85.10-C85.99	Other specified and unspecified types of non-Hodgkin lymphomas
C86.0-C86.6	Other specified types of T/NK-cell lymphoma
C88.0-C88.9	Malignant immunoproliferative diseases and certain other B-cell lymphomas
C90.00-C90.32	Multiple myeloma and malignant plasma cell neoplasms
C91.00-C91.92	Lymphoid leukemia
C92.00-C92.92	Myeloid leukemia
C93.00-C93.92	Monocytic leukemia
C94.00-C94.82	Other leukemias of specified cell type
C95.00-C95.92	Leukemia of unspecified cell type
C96.0-C96.9	Other and unspecified malignant neoplasms of lymphoid, hematopoietic and related tissue
D39.2	Neoplasm of uncertain behavior of placenta
D45	Polycythemia vera
D46.0-D46.Z	Myelodysplastic syndromes
D47.01	Cutaneous mastocytosis
D47.02	Systemic mastocytosis
D47.09	Other mast cell neoplasms of uncertain behavior
D47.1	Chronic myeloproliferative disease
D47.2	Monoclonal gammopathy

D47.3	Essential (hemorrhagic) thrombocythemia
D47.4	Osteomyelofibrosis
D47.9	Neoplasm of uncertain behavior of lymphoid, hematopoietic and related tissue, unspecified
D47.Z1	Post-transplant lymphoproliferative disorder (PTLD)
D47.Z2	Castleman disease
D47.Z9	Other specified neoplasms of uncertain behavior of lymphoid, hematopoietic and related tissue
D50.0-D50.9	Iron deficiency anemia
D51.0-D51.9	Vitamin B12 deficiency anemia
D52.9	Folate deficiency anemia, unspecified
D53.0-D53.9	Other nutritional anemias
D56.0-D56.9	Thalassemia
D57.00-D57.819	Sickle-cell disorders
D58.0	Hereditary spherocytosis
D58.2	Other hemoglobinopathies
D58.9	Hereditary hemolytic anemia, unspecified
D59.0-D59.9	Acquired hemolytic anemia
D60.0-D60.9	Acquired pure red cell aplasia (erythroblastopenia)
D61.01-D61.9	Other aplastic anemias and other bone marrow failure syndromes
D62	Acute post-hemorrhagic anemia
D63.0-D63.8	Anemia in chronic diseases classified elsewhere
D64.0-D64.9	Other anemias
D68.51	Activated protein C resistance
D68.52	Prothrombin gene mutation
D68.59	Other primary thrombophilia
D68.61	Antiphospholipid syndrome
D68.62	Lupus anticoagulant syndrome
D68.69	Other thrombophilia
D69.0-D69.9	Purpura and other hemorrhagic conditions
D70.0-D70.9	Neutropenia
D71	Functional disorders of polymorphonuclear neutrophils
D72.0-D72.9	Other disorders of white blood cells
D73.0-D73.9	Diseases of spleen
D75.0-D75.9	Other and unspecified diseases of blood and blood-forming organs
D76.1-D76.3	Other specified diseases with participation of lymphoreticular and reticulohistiocytic tissue
D77	Other disorders of blood and blood-forming organs in diseases classified elsewhere
D80.0	Hereditary hypogammaglobulinemia
D80.0-D80.9	Immunodeficiency with predominantly antibody defects
D81.0-D81.9	Combined immunodeficiencies
D82.0-D82.9	Immunodeficiency associated with other major defects
D83.0-D83.9	Common variable immunodeficiency
D84.0-D84.9	Other immunodeficiencies
D86.0	Sarcoidosis of lung
D86.1	Sarcoidosis of lymph nodes
D86.2	Sarcoidosis of lung with sarcoidosis of lymph nodes
D86.85	Sarcoid myocarditis
D89.0-D89.9	Other disorders involving the immune mechanism, not elsewhere classified
E34.0	Carcinoid syndrome
E85.0-E85.9	Amyloidosis
E88.01	Alpha-1-antitrypsin deficiency
E88.02	Plasminogen deficiency
E88.09	Other disorders of plasma-protein metabolism, not elsewhere classified
G93.49	Other encephalopathy
I89.0-I89.9	Other non-infective disorders of lymphatic vessels and lymph node
J90	Pleural effusion, not elsewhere classified
J91.0	Malignant pleural effusion
J91.8	Pleural effusion in other conditions classified elsewhere
J94.0	Chylous effusion
M02.30-M02.39	Reiter's disease

O01.1-O01.9	Hydatidiform mole
O02.0	Blighted ovum and nonhydatidiform mole
O98.71	Human immunodeficiency virus [HIV] disease complicating pregnancy
R59.0-R59.9	Enlarged lymph nodes
R64	Cachexia
R75	Inconclusive laboratory evidence of human immunodeficiency virus [HIV]
R76.9	Abnormal immunological finding in serum, unspecified
T86.00-T86.99	Complications of transplanted organs and tissue [postoperative monitoring]
Z21	Asymptomatic human immunodeficiency virus [HIV] infection status
Z48.21-Z48.298	Encounter for aftercare following organ transplant
Z52.001	Unspecified donor, stem cells
Z52.011	Autologous donor, stem cells
Z52.091	Other blood donor, stem cells
Z52.3	Bone marrow donor
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-Z94.9	Transplanted organ and tissue status [postoperative monitoring]

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