Genomic/Genetic/Biomarker/Tumor Marker Tests

POLICY NUMBER UM ONC_1394	**SUBJECT** Genomic/Genetic/Biomarker/Tumor Marker Tests	**DEPT/PROGRAM** UM Dept	**PAGE 1 OF 3**
DATES COMMITTEE REVIEWED 05/13/20, 04/14/21, 04/13/22, 03/08/23, 03/13/24	**APPROVAL DATE** March 13, 2024	**EFFECTIVE DATE** March 29, 2024	**COMMITTEE APPROVAL DATES** 05/13/20, 04/14/21, 04/13/22, 03/08/23, 03/13/24
PRIMARY BUSINESS OWNER: UM		**COMMITTEE/BOARD APPROVAL** Utilization Management Committee	
NCQA STANDARDS UM 2		**ADDITIONAL AREAS OF IMPACT**	
CMS REQUIREMENTS	**STATE/FEDERAL REQUIREMENTS**	**APPLICABLE LINES OF BUSINESS** Commercia, Exchange, Medicaid	

I. PURPOSE

To define and describe the accepted indications and clinical criteria applied to requests for serum and tissue markers for medical necessity.

II. DEFINITIONS

Biomarker: A specific biological abnormality found in blood, other body fluids, or tissues that is a sign of a condition or disease. A biomarker may be used to help prevent, diagnose, or treat a condition and/or to see how well the body responds to a treatment for a disease or condition. The term "biomarker" is generally interchangeable with the term molecular marker.

Genomic Tests/Biomarker Analysis/Molecular Testing These tests are performed on tumor tissue, and/or blood (which often has circulating tumor DNA). Genomic tests look for specific DNA-level (genomic) abnormalities in tumor tissue. A variety of methods may be utilized to perform these tests, such as NGS-Next Generation Sequencing. The term " Biomarker" is an umbrella term that includes both genomic (e.g., EGFR mutation) and non-genomic (e.g., PD-L1 expression) abnormalities in tumor tissue. The term "Companion Diagnostics" refers to a specific test that is required prior to the approval of a specific drug/agent. A list of Companion Diagnostic Tests and Pharmacogenomic Biomarkers is maintained by the FDA at https://www.fda.gov/drugs/science-and-research-drugs/table-pharmacogenomic-biomarkers-drug-labeling.

Next-Generation Sequencing (NGS) A high-throughput method used to analyze the genome (DNA) of tumor tissue and or circulating tumor cells or cell-free DNA. This technique utilizes DNA sequencing technologies that are capable of processing multiple DNA sequences in parallel. Also called massively parallel sequencing and NGS.

Genetic Testing: Genetic testing looks for specific inherited changes (variants) in a person's genes and may be used to help guide individualized patient care. Genetic variants can have harmful/beneficial or no effects on the body. Harmful variants in some genes are known to be

associated with an increased risk of developing cancer. These inherited variants are thought to contribute to about 5 to 10% of all cancers. See paragraph below for details.

Hereditary Cancer Syndrome/Inherited cancer susceptibility syndromes: A type of inherited disorder in which there is a higher-than-normal risk of certain types of cancer. Hereditary cancer syndromes are caused by aberrations/structural changes (e.g., mutations) in certain genes passed from parents to children. In a hereditary cancer syndrome, certain patterns of cancer may be seen within families. These patterns include having several close family members (such as a mother, daughter, and sister) with the same type of cancer, developing cancer at an early age, or having two or more types of cancer develop in the same person. Examples of hereditary cancer syndromes are hereditary breast and ovarian cancer syndrome, Li-Fraumeni syndrome, Cowden syndrome, and Lynch syndrome.

III. POLICY

A. Evolent authorizes genetic, genomic, and biomarker test requests when results of said tests would impact therapeutic decision making, and peer reviewed literature/clinical evidence supports the need for such testing.

B. Evolent utilizes the National Comprehensive Cancer Network (NCCN) Biomarkers Compendium® and/or FDA Pharmacogenomic Biomarkers listing as the primary clinical criteria for determinations. If NCCN Biomarkers Compendium or FDA Biomarker listing is silent on testing and/or indication for requested use, Evolent will utilize ASCO Clinical Guidelines, and other sources of peer reviewed literature for clinical criteria in making determinations.

C. Benefit coverage of test(s) is determined by health care benefit plan policy and insurance coverage for a service. This policy describes requirements to meet clinical criteria and medically necessity for the above tests.

IV. PROCEDURE

A. Requests for genetic/genomic/biomarker testing are considered appropriate per the National Comprehensive Cancer Network (NCCN) Biomarkers Compendium® and/or FDA Pharmacogenomic Biomarkers listing for the patient's condition, based on the following:

   1. The patient's diagnosis matches the Disease Description field and requested test matches the Molecular Abnormality and Gene Symbol fields.
   2. The patient's diagnosis, stage and extent of disease and appropriate workup and sequencing of tests as outlined in the NCCN Recommendation: Clinical Decision field.
   3. For Genetic testing request- for a suspected hereditary cancer syndrome- NCCN guidelines for such testing and or the patient's family history should support the request.

B. NCCN Category of Evidence and Consensus is 1 or 2A.

   1. Category 1 Based upon high-level evidence, there is uniform NCCN consensus (85%) that the intervention is appropriate.
   2. Category 2A Based upon lower-level evidence, there is uniform NCCN consensus (85%) that the intervention is appropriate.
   3. Requests that meet the clinical criteria for use with category 1 and 2A evidence are authorized by Peer Clinical Reviewers.

C. Clinical review and/or peer discussion are required for testing requests with a NCCN Category of Evidence and Consensus 2B or 3.
    1. Category 2B Based upon lower-level evidence, there is NCCN consensus (50%-85%) that the intervention is appropriate.
    2. Category 3 Based upon any level of evidence, there is major NCCN disagreement (at least 3 institutions) that the intervention is appropriate.
    3. Additional resources to determine clinical validity, utility, and efficacy to target a patient's specific condition or impact clinical decision-making and care can include but not be limited to FDA List of Cleared or Approved Companion Diagnostics Devices (In Vitro and Imaging Tools), peer-reviewed medical literature, and individual patient clinical condition.
    4. Requests with category 2B and 3 level of evidence require peer clinical reviewer and may require peer-to-peer discussion with the requesting provider prior to Evolent issuing a determination of approval or recommended adverse determination for the request.
D. All submitted requests for authorization follow existing Evolent policies for determinations, timeframes, documentation, and notification.

V. APPROVAL AUTHORITY

A. Review – Utilization Management Department
B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

A. None

VII. REFERENCES

A. National Comprehensive Cancer Network (NCCN). The NCCN Biomarkers Compendium (NCCN Compendium). https://www.nccn.org/professionals/biomarkers/content/ [Accessed February 7,, 2023].
B. U.S. Food & Drug Administration Table of Pharmacogenomic Biomarkers in Drug Labeling: https://www.fda.gov/drugs/science-and-research-drugs/table-pharmacogenomic-biomarkers-drug-labeling. [AccessedFebruary 7, 2023].
C. US FDA. List of Cleared or Approved Companion Diagnostic Devices (In Vitro and Imaging Tools). Updated: January 8, 2020 Available online: https://www.fda.gov/medical-devices/vitro-diagnostics/list-cleared-or-approved-companion-diagnostic-devices-vitro-and-imaging-tools [Accessed February 7, 2023].