Maryland
DEPARTMENT OF HEALTH

81445, 81450, 81455 (Genomic Sequencing Procedures and Other Molecular Multianalyte Assays)

A genomic sequence analysis panel to evaluate the patient specimen for targeted genetic sequences known to relate to solid organ cancers or to blood or lymph cancers known as hematolymphoid neoplasms.

Preauthorization is Required for:

- CPT 81445 - applies to solid organ neoplasm type (5-50 genes).
- CPT 81450- applies to hematolymphoid neoplasm type (5-50 genes).
- CPT 81455 - applies to the number of genes analyzed for either a solid or hematolymphoid neoplasm (51 or greater genes).

I. Criteria for Approval

The goal of genomic test panels for cancer is to identify molecular genetic alterations that, in the appropriate context, provide clinical benefit; either in terms of establishing a diagnosis, selecting a molecularly-targeted therapy, or determining prognosis in a way that has a tangible patient impact (influencing therapeutic decisions such as whether or not to undergo a bone marrow transplant, a high intensity chemotherapeutic or radiotherapy regimen, surgical procedures, or palliative care).

Molecular panel testing to identify targeted therapy may be considered medically necessary when utilized for some cancer types. CPT Codes: 81455, 81445, and 81450 will be considered for coverage when **ALL** of the criteria below are met, confirmed with supporting medical documentation.

Supporting documentation:

- A copy of the patient's medical record supporting the medical necessity for the request for molecular panel testing. This should include the patient's clinical diagnosis and current condition, medical treatment to date, and previous pertinent medical treatments including all current lab tests that support the request.
- Documentation must include a statement of how the particular molecular panel test results will directly alter the treatment and/or medical management of the patient's diagnosed condition. The use of a particular molecular panel may also be considered medically necessary to exclude the use of ineffective targeted therapies when supported by the medical literature.

- The request must be made by the patient's oncology provider with support, or in conjunction with, counseling by a medical geneticist or a board-certified genetic counselor.

II. What is Excluded From Coverage

- Testing, for the purpose of confirming a suspected diagnosis that can be diagnosed based on clinical evaluations alone, will not be covered.
- Genetic testing, when the clinical utility is not scientifically supported.
- Testing for conditions, which cannot be altered by a specific treatment or prevented by specific interventions.
- Providers may **not** report 81455 with either 81445 or 81450.

II. Billing Code/Information

81445	Targeted genomic sequence analysis panel, solid organ neoplasm, DNA analysis, 5-50 genes (e.g., ALK, BRAF, CDKN2A, EGFR, ERBB2, KIT, KRAS, NRAS, MET, PDGFRA, PDGFRB, PGR, PIK3CA, PTEN, RET), interrogation for sequence variants and copy number variants or rearrangements, if performed.
81450	Targeted genomic sequence analysis panel, hematolymphoid neoplasm or disorder, DNA and RNA analysis when performed, 5-50 genes (e.g., BRAF, CEBPA, DNMT3A, EZH2, FLT3, IDH1, IDH2, JAK2, KRAS, KIT, MLL, NRAS, NPM1, NOTCH1), interrogation for sequence variants, and copy number variants or rearrangements, or isoform expression or mRNA expression levels, if performed.
81455	Targeted genomic sequence analysis panel, solid organ or hematolymphoid neoplasm, DNA and RNA analysis when performed, 51 or greater genes (e.g., ALK, BRAF, CDKN2A, CEBPA, DNMT3A, EGFR, ERBB2, EZH2, FLT3, IDH1, IDH2, JAK2, KIT, KRAS, MLL, NPM1, NRAS, MET, NOTCH1, PDGFRA, PDGFRB, PGR, PIK3CA, PTEN, RET), interrogation for sequence variants and copy number variants or rearrangements, if performed.

Prior authorization of benefits is not the practice of medicine nor the substitute for the independent medical judgment of a treating medical provider. The materials provided are a component used to assist in making coverage decisions and administering benefits. Prior authorization does not constitute a contract or guarantee regarding member eligibility or payment. Prior authorization criteria are established based on a collaborative effort using input from the current medical literature and based on evidence available at the time.

Approved by MDH Clinical Criteria Committee: 1/25/2022
Last Reviewed Date: 1/25/2022