Status
Active

Medical and Behavioral Health Policy
Section: Laboratory
Policy Number: VI-49
Effective Date: 10/20/2014

EXPANDED MOLECULAR PANEL TESTING OF CANCERS TO IDENTIFY TARGETED THERAPIES

Description: This policy addresses use of expanded panels which are defined as panels that test a wide variety of genetic markers in cancers without regard for whether specific targeted treatment has demonstrated benefit. This approach may result in a different treatment than usually selected for a patient based on the type of cancer and its stage. The policy is not intended to address the use of tests for individual markers or cancer-specific panels that include a few mutations.

Tumor location, grade, stage and the patient's underlying physical condition have traditionally been used in clinical oncology to determine the therapeutic approach to a specific cancer. Therapies may include surgical resection, ionizing radiation, systemic or oral chemotherapy, or a combination of approaches. The traditional approach to cancer treatment does not reflect the wide diversity of cancer at the molecular level. Using genetic markers, cancers can be further classified by pathways defined at the molecular level. Targeted cancer therapies utilize identification of genetic mutations that are present in the cancer of a particular patient to determine use of drugs that target the specific mutation.

Currently, there are a small number of individual genetic markers identified in clinical trials that have a direct impact on care for a specific cancer of interest. In some cases, limited panels may be offered that are specific to one particular type of cancer. An example of this is a panel of several markers for non-small cell lung cancer.

There are no U.S. Food and Drug Administration (FDA)-approved genetic panels for targeted cancer treatment. Commercially available panels are laboratory-developed tests that are not subject to FDA approval. Clinical laboratories may develop and validate tests in-

house (“home-brew”) and market them as a laboratory service. Such tests must meet the general regulatory standards of the Clinical Laboratory Improvement Amendments (CLIA).

Examples of Expanded Molecular Panels:

Expanded molecular panels include but are not limited to the following:

- The FoundationOne™ test analyzes 315 cancer-related genes and select introns from an additional 28 genes using next generation sequencing. The test can be performed on a surgical biopsy or a needle biopsy of a solid tumor.
- The FoundationOne™ Heme Test is a panel that is intended for use in hematologic malignancies. It analyzes 405 cancer-related genes and selected introns from an additional 31 genes. In addition, RNA sequencing of 265 genes is done to test for common rearrangements resulting from gene fusion.
- The TruSeq® Amplicon Panel (Illumina) analyzes 48 cancer-related genes by next-generation sequencing.
- The TruSight™ Tumor Panel (Illumina) analyzes 26 cancer-related genes associated with solid tumors.
- The Ion AmpliSeq™ Comprehensive Cancer Panel (Life Technologies, Inc.) analyzes more than 400 cancer-related genes and tumor suppressor genes.
- The Ion AmpliSeq™ Cancer Hotspot Panel v2 (Life Technologies, Inc.) analyzes the “hotspot” regions of 50 cancer-related and tumor suppressor genes.

Definitions:

Gene fusion: This occurs when two separate genes combine due to changes within the genes or chromosomes. This may lead to a gene product with different functions than either of the two original genes. Some fused genes have been found to lead to cancer and other disease. However, the clinical implications of many gene fusions, either for diagnosis or treatment selection, are not known.

Expanded molecular panels test a wide variety of genetic markers in cancers without regard for whether specific targeted treatment has demonstrated benefit. This approach may result in a different treatment than usually selected for a patient based on the type of cancer and its stage.

Intron: The non-coding sequence of DNA removed from mature messenger RNA prior to translation. DNA initially transcribed to messenger RNA consists of coding sequences (exons) and non-coding sequences (introns); introns are spliced out of the messenger RNA prior to translation, leaving only the exons to ultimately encode the amino acid product.

Next generation sequencing refers to one of several methods that use massively parallel platforms to allow the sequencing of large numbers of DNA segments.

Policy: The use of expanded molecular panel testing of cancers to identify targeted therapies as described above is considered **INVESTIGATIVE** due to a lack of evidence demonstrating an impact on improved health outcomes.

Coverage: Blue Cross and Blue Shield of Minnesota medical policies apply generally to all Blue Cross and Blue Plus plans and products. Benefit plans vary in coverage and some plans may not provide coverage for certain services addressed in the medical policies.

Medicaid products and some self-insured plans may have additional policies and prior authorization requirements. Receipt of benefits is subject to all terms and conditions of the member's summary plan description (SPD). As applicable, review the provisions relating to a specific coverage determination, including exclusions and limitations. Blue Cross reserves the right to revise, update and/or add to its medical policies at any time without notice.

For Medicare NCD and/or Medicare LCD, please consult CMS or National Government Services websites.

Refer to the Pre-Certification/Pre-Authorization section of the Medical Behavioral Health Policy Manual for the full list of services, procedures, prescription drugs, and medical devices that require Pre-certification/Pre-Authorization. Note that services with specific coverage criteria may be reviewed retrospectively to determine if criteria are being met. Retrospective denial of claims may result if criteria are not met.

Coding: *The following codes are included below for informational purposes only, and are subject to change without notice. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement.*

CPT:

81479 Unlisted molecular pathology procedure

Policy History: **Developed August 13, 2014**

Cross Reference: