MEDICAL POLICY – 12.04.115
Expanded Molecular Panel Testing of Cancers to Identify Targeted Therapies

BCBSA Ref. Policy: 2.04.115
Effective Date: Nov. 1, 2016
Last Revised: Oct. 6, 2017
Replaces: 2.04.115

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Introduction

Medical studies have shown that doing specific genetic tests on certain tumors is useful in choosing which treatment to use. These genetic tests look for the presence or absence of known genetic changes. The results can be used to match a person to the therapy that will be most helpful. There are other types of genetic tests that look at a very large number of genes. These tests are known as expanded molecular panels. They can test hundreds of genes. The difficulty with expanded molecular panels is that most of the genetic markers tested haven’t been shown to affect either cancer growth or cancer therapies. Because more study is needed, expanded molecular panels are considered investigational.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria
## Test

<table>
<thead>
<tr>
<th>Test</th>
<th>Investigational</th>
</tr>
</thead>
<tbody>
<tr>
<td>Expanded cancer mutation panels</td>
<td>The use of expanded cancer mutation panels is considered investigational for selecting targeted cancer treatment.</td>
</tr>
</tbody>
</table>

## Coding

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>CPT</td>
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<tr>
<td>0017U</td>
<td>Oncology (hematolymphoid neoplasia), JAK2 mutation, DNA, PCR amplification of exons 12-14 and sequence analysis, blood or bone marrow, report of JAK2 mutation not detected or detected (new code effective 8/1/17)</td>
</tr>
<tr>
<td>81445</td>
<td>Targeted genomic sequence analysis panel, solid organ neoplasm, DNA analysis, and RNA analysis when performed, 5-50 genes (eg, ALK, BRAF, CDKN2A, EGFR, ERBB2, KIT, KRAS, NRAS, MET, PDGFRα, PDGFRβ, PGR, PIK3α, PTEN, RET), interrogation for sequence variants and copy number variants or rearrangements, if performed</td>
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<tr>
<td>81450</td>
<td>Targeted genomic sequence analysis panel, hematolymphoid neoplasm or disorder, DNA analysis, and RNA analysis when performed, 5-50 genes (eg, BRAF, CEBPA, DNMT3A, EZH2, FLT3, IDH1, IDH2, JAK2, KRAS, KIT, MLL, NRAS, NPM1, NOTCH1), interrogation for sequence variants, and copy number variants or rearrangements, isoform expression or mRNA expression levels, if performed</td>
</tr>
<tr>
<td>81455</td>
<td>Targeted genomic sequence analysis panel, solid organ or hematolymphoid neoplasm, DNA analysis, and RNA analysis when performed, 51 or greater genes (eg, ALK, BRAF, CDKN2A, CEBPA, DNMT3A, EGR, ERBB2, EZH2, FLT3, IDH1, IDH2, JAK2, KIT, KRAS, MLL, NPM1, NRAS, MET, NOTCH1, PDGFRα, PDGFRβ, PGR, PIK3α, PTEN, RET), interrogation for sequence variants and copy number variants or rearrangements, if performed</td>
</tr>
<tr>
<td>81479</td>
<td>Unlisted molecular pathology procedure</td>
</tr>
</tbody>
</table>

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Genetic Counseling

Genetic counseling is primarily aimed at patients who are at risk for inherited disorders, and experts recommend formal genetic counseling in most cases when genetic testing for an inherited condition is considered. The interpretation of the results of genetic tests and the understanding of risk factors can be very difficult and complex. Therefore, genetic counseling will assist individuals in understanding the possible benefits and harms of genetic testing, including the possible impact of the information on the individual's family. Genetic counseling may alter the utilization of genetic testing substantially and may reduce inappropriate testing. Genetic counseling should be performed by an individual with experience and expertise in genetic medicine and genetic testing methods.

Evidence Review

Description

Currently, there is interest in treating cancers by targeting biological “pathways” that are characterized by specific genetic markers. Genetic panel testing offers the potential to evaluate a large number of genetic markers at a single time to identify treatments that target specific pathways. There are some individual markers that have established benefit in certain types of cancers; these situations are not addressed in this medical policy. Rather, the focus of this policy is on “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 treatment different than that usually selected for a patient based on the type of cancer and stage.

Background

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, which could include surgical resection, ionizing radiation, systemic chemotherapy, or combinations thereof. Currently, some 100 different types are broadly categorized according to the tissue, organ, or body compartment in which it arises. Most treatment approaches in clinical care were
developed and evaluated in studies that recruited subjects and categorized results based on this traditional classification scheme.

This traditional approach to cancer treatment does not reflect the wide diversity of cancer at the molecular level. While treatment by organ type, stage, and grade may demonstrate statistically significant therapeutic efficacy overall, only a subgroup of patients may actually derive clinically significant benefit. It is unusual for a cancer treatment to be effective for all patients treated in a traditional clinical trial. Spear et al analyzed the efficacy of major drugs used to treat several important diseases. They reported heterogeneity of therapeutic responses ranging from a low of 25% for cancer chemotherapeutics to as high as 80% for medications such as COX-2 inhibitors, with response rates for most drugs falling in the range of 50% to 75%. The low rate for cancer treatments is indicative of the need for better identification of characteristics associated with treatment response and better targeting of treatment in order to have higher rates of therapeutic responses.

Much of the variability in clinical response may result from genetic variations. Within each broad type of cancer, there may be a large amount of variability in the genetic underpinnings of the cancer. Targeted cancer treatment refers to the identification of genetic abnormalities present in the cancer of a particular patient, and the use of drugs that target the specific genetic abnormality. Using genetic markers, cancers can be further classified by “pathways” defined at the molecular level. An expanding number of genetic markers have been identified. Dienstmann et al categorized these findings into 3 classes. These are: (1) Genetic markers that have a direct impact on care for the specific cancer of interest, (2) Genetic markers that may be biologically important but are not currently actionable, and (3) Genetic markers of unknown importance.

A smaller number of individual genetic markers fall into the first category, ie, have established utility for a particular cancer type). Utility of these markers has generally been demonstrated by randomized controlled trials that select patients with the marker, and report significant improvements in outcomes with targeted therapy compared with standard therapy. This medical policy does not apply to the individual markers that have demonstrated efficacy. According to recent National Comprehensive Cancer Network guidelines, the following markers have demonstrated utility for predicting treatment response to targeted therapies for the specific cancers listed:

- Breast cancer
  - HER2 (ERBB2)
- Colon cancer
  - RAS mutations (KRAS, NRAS)
- BRAF c1799T>A
- Non-small-cell lung cancer (NSCLC)
  - EGFR
  - ALK/ROS1
  - KRAS
- Metastatic melanoma
  - BRAF v600
- Ovarian cancer
- BRCA (germline)
- Chronic myeloid leukemia
  - BRC-ABL
- Gastrointestinal stromal tumors
  - KIT

Testing for these individual mutations with established utility is not covered in this medical policy.

In some cases, limited panels may be offered that are specific to 1 type of cancer (eg, a panel of several markers for non-small cell lung cancer (NSCLC). This policy is does not address the use of these cancer-specific panels that include a few mutations. The intent is to address expanded panels that test for many potential mutations that do not have established efficacy for the specific cancer in question.

When advanced cancers are tested with expanded mutation panels, most patients are found to have at least 1 potentially pathogenic mutation. The number of mutations varies widely by types of cancers, different mutations included in testing, and different testing methods among the available studies. In a 2015 study, 439 patients with diverse cancers were tested with a 236-gene panel. A total of 1,813 molecular alterations were identified, and almost all patients (420/439 [96%]) had at least 1 molecular alteration. Median number of alterations per patient was 3, and 85% of patients (372/439) had 2 or more alterations. The most common alterations were in the genes TP53 (44%), KRAS (16%), and PIK3CA (12%).
Some evidence is available on the generalizability of targeted treatment based on a specific mutation among cancers that originate from different organs.\(^2\,^3\,^7\) There are several examples of mutation-directed treatment that was effective in 1 type of cancer but ineffective in another. For example, targeted therapy for epidermal growth factor receptor (EGFR) mutations has been successful in NSCLC but not in trials of other cancer types. Treatment with tyrosine kinase inhibitors based on mutation testing has been effective for renal cell carcinoma, but has not demonstrated effectiveness for other cancer types tested. “Basket” studies, in which tumors of various histologic types that share a common genetic mutation are treated with a targeted agent, also have been performed. One such study was published in 2015 by Hyman et al.\(^8\) In this study, 122 patients with BRAF V600 mutations in nonmelanoma cancers were treated with vemurafenib. The authors reported that there appeared to be antitumor activity for some but not all cancers, with the most promising results seen for NSCLC, Erdheim-Chester disease, and Langerhans cell histiocytosis.

**Expanded Cancer Mutation Panels**

The **FoundationOne™** test (Foundation Medicine, Cambridge, MA)\(^9\) is a targeted mutation panel intended for use with solid tumors. It analyzes 236 cancer-related genes and 47 introns from an additional 19 genes using next-generation sequencing (NGS) technology. The test identifies a number of types of mutations, including base substitutions, duplications/deletions, copy number variations (CNVs), and rearrangements. The test can be performed on a surgical or a needle biopsy of a solid tumor that contains at least 40 μm of tissue, 20% of which must be malignant material.

The **FoundationOne Heme** test (Foundation Medicine)\(^9\) is a similar 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.

**OnkoMatch** (GenPath Diagnostics) is a polymerase chain reaction (PCR)–based gene panel that detects 68 mutations (single nucleotide polymorphisms) in 14 oncogenes and tumor suppressor genes that are associated with solid tumors (AKT1, APC, BRAF, CTNNB1 [beta-catenin], EGFR, IDH1, KIT, KRAS, MAP2K1, NOTCH1, NRAS, PIK3CA, PTEN, TP53). The product brochure (available on the manufacturer’s website)\(^10\) states that OnkoMatch is intended for use in patients with lung, breast, colon, gastrointestinal, pancreatic, head and neck, ovarian, or thyroid cancers, or melanoma. Test developers recommend its use “to support diagnostic and treatment decisions and to facilitate clinical trial enrollment.” GenPath also lists OnkoMatch Plus for Lung and OnkoMatch Plus for ALK-Negative Lung in its test catalog.\(^11\)
**GeneTrails Solid Tumor Panel** (Knight Diagnostic Labs, Portland OR) consists of 37 genes that are known to have mutations in solid tumors. Of the 37 mutations, 20 have known targetable treatments based on the presence or absence of mutations, and 17 have mutations that might indicate eligibility for ongoing clinical trials. According to the manufacturer, this test is intended for patients with adenocarcinomas (colon, small intestine, stomach, esophagus), squamous cell carcinomas (lung, head neck, esophagus, cervix), BRAF-negative melanomas, cholangiocarcinoma, and carcinomas of the endometrium, ovaries, salivary glands, urothelium, and adrenal cortices.

**Molecular Intelligence®** tumor profiling (Caris Life Sciences, Irving, TX) offers services that analyzes of up to 56 tumor-associated genes. According to the manufacturer's website, panels with specific genes are not listed, but customized panels are available according to patients' clinical information and cancer type. The panels use a variety of technologies, including NGS, immunohistochemistry, fluorescence in situ hybridization, Sanger sequencing, pyrosequencing, quantitative PCR, and fragmentation analysis.

**SmartGenomics™** (PathGroup, Brentwood TN) offers testing of up to 62 cancer-associated genes using a combination of NGS, cytogenomic array, and other technologies. The test is intended for use in a wide variety of solid and hematologic tumors to identify targeted treatments and to assess eligibility for clinical trials.

**Guardant360** panel (GuardantHealth, Redwood City, CA) analyzes 68 genes associated with solid tumors. It is intended for a wide variety of solid tumors. This panel uses novel technology to analyze cell-free DNA present in the circulating blood rather than analyzing a tumor sample. The manufacturer’s website refers to “digital sequencing” using information technology, but there is a lack of published studies that evaluate the analytic validity of this technique.

**Paradigm Cancer Diagnostic** (PcDx) Panel (Paradigm, Ann Arbor, MI) is a NGS-based panel that evaluates more than 500 genetic “targets.” Targets include point mutations, deletions, CNVs, fusions, mRNA expression, and protein expression. The test is intended for patients with a wide variety of cancers refractory to standard care.

**MSK-IMPACT™** (Memorial Sloan Kettering-Integrated Mutation Profiling of Actionable Cancer Target) consists of 341 cancer associated genes. It is a hybridization capture-based NGS assay that detects mutations, CNVs, and structural rearrangements. This test offers paired analysis of tumor tissue with matched normal tissue to determine whether mutations are truly somatic cancer mutations.

A number of other targeted panels primarily marketed to researchers include:
• Illumina Inc. (San Diego, CA) offers several cancer panels. The TruSeq® Amplicon Panel analyzes 48 cancer-related genes by NGS. The Illumina TruSight™ Tumor Panel analyzes 26 cancer-related genes associated with solid tumors.

• Life technologies offers several variations of its Ion AmpliSeq™ panels intended for use in cancer. The Ion AmpliSeq Comprehensive Cancer Panel analyzes more than 400 cancer-related genes and tumor suppressor genes. The Ion AmpliSeq Cancer Hotspot Panel v2 analyzes the “hotspot” regions of 50 cancer-related and tumor suppressor genes.

**Summary of Evidence**

The evidence for the use of expanded mutation panels to direct targeted cancer treatment includes one randomized controlled trial (RCT), several nonrandomized trials, and numerous case series. Relevant outcomes are overall survival, disease-specific survival, test accuracy and validity, and other test performance measures. The analytic validity of these panels is likely to be high when next-generation sequencing is used. The clinical validity of the individual mutations for particular types of cancer is not easily obtained from the available published literature. The large number of mutations and many different types of cancer preclude determination of clinical validity for the panels as a whole. Some evidence reports that many of the identified mutations are false positives (ie, not biologically active), after filtering by comparison with matched normal tissue and cancer mutation databases. To demonstrate clinical utility, RCTs are needed that compare the strategy of targeted treatment based on panel results with standard care. The first such RCT published, the SHIVA trial, reported that there was no difference in progression-free survival when panels were used in this way. Some nonrandomized comparative studies, comparing matched treatment with non-matched treatment, have reported that outcomes are superior for patients receiving matched treatment. However, these studies are inadequate to determine treatment efficacy because the populations with matched and unmatched cancers may differ on several important clinical and prognostic variables. In addition, there is potential for harm if ineffective therapy is given based on test results, because there may be adverse effects of therapy in absence of a benefit. The evidence is insufficient to determine the effects of the technology on health outcomes.
Practice Guidelines and Position Statements

National Comprehensive Cancer Network (NCCN)

The NCCN guidelines do not contain recommendations for the general strategy of testing a tumor for a wide range of mutations. The guidelines do contain recommendations for specific genetic testing for individual cancers, based on situations where there is a known mutation-drug combination that has demonstrated benefits for that specific tumor type. Some examples of recommendations for common solid tumors are listed next:

- **Breast cancer**
  - HER2 testing, when specific criteria are met

- **Colon cancer**
  - KRAS/NRAS testing for patients with metastatic colon cancer
  - Consider BRAF V600E testing for patients with metastatic colon cancer

- **Non-small-cell lung cancer**
  - KRAS, EGFR [epidermal growth factor receptor], and ALK [anaplastic lymphoma kinase] testing for patients with metastatic adenocarcinoma
  - Consider EGFR and ALK testing especially in never smokers, mixed histology, or small biopsy specimen

- **Melanoma**
  - BRAF V600 testing for patients with metastatic disease

Medicare National Coverage

There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.
Regulatory Status

Clinical laboratories may develop and validate tests in-house and market them as a laboratory service; laboratory-developed tests (LDTs) must meet the general regulatory standards of the Clinical Laboratory Improvement Act (CLIA). Laboratories that offer LDTs must be licensed by CLIA for high-complexity testing. To date, the U.S. Food and Drug Administration has chosen not to require any regulatory review of this test.

References


<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
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<tbody>
<tr>
<td>05/12/14</td>
<td>New Policy. New policy created with literature review through February 15, 2014. The use of expanded mutation panels to direct targeted treatment is considered investigational.</td>
</tr>
<tr>
<td>10/13/14</td>
<td>Interim Update. Molecular Intelligence panel added as investigational. Reference added. Code range 81200 – 81409 removed, along with ICD-10-CM code. These are not specific to the policy.</td>
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<tr>
<td>02/10/15</td>
<td>Policy moved to genetic testing section and renumbered 12.04.115 (previously 2.04.115); was previously miscategorized.</td>
</tr>
<tr>
<td>06/17/15</td>
<td>Annual Review. Policy updated with literature review through April 4, 2015. References 6-11 added, and references 20-23 updated. No change to policy statements.</td>
</tr>
<tr>
<td>12/08/15</td>
<td>Interim Update. Policy updated with literature review through September 30, 2015; references 4, 6, 8, 16-17, 21, 23, and 26 added. Policy statement unchanged. Title changed to “Expanded Molecular Panel Testing of Cancers to Identify Targeted Therapies”.</td>
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<tr>
<td>05/04/16</td>
<td>Update related policies. 12.04.92 was deleted and replaced with 12.04.520.</td>
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<tr>
<td>06/24/16</td>
<td>Minor update. Removed 81210 from list of examples in the Coding section.</td>
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<tr>
<td>08/01/16</td>
<td>Coding update. Added CPT codes 81445, 81450, and 81455.</td>
</tr>
<tr>
<td>01/01/17</td>
<td>Updated Related Policies, removed 12.04.520 as it was archived.</td>
</tr>
<tr>
<td>07/07/17</td>
<td>Policy moved into new format, no changes to policy statement.</td>
</tr>
<tr>
<td>10/06/17</td>
<td>Coding update; added new CPT code 0017U, effective 8/1/17.</td>
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U.S. Department of Health and Human Services
200 Independence Avenue SW, Room 509F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)
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