### MEDICAL POLICY – 12.04.115

**Expanded Molecular Panel Testing of Cancers to Identify Targeted Therapies**

<table>
<thead>
<tr>
<th>BCBSA Ref. Policy:</th>
<th>2.04.115</th>
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<tr>
<td>Effective Date:</td>
<td>Dec. 1, 2017</td>
</tr>
<tr>
<td>Last Revised:</td>
<td>May 19, 2018</td>
</tr>
<tr>
<td>Replaces:</td>
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**RELATED MEDICAL POLICIES:**

- 12.04.93 Genetic Cancer Susceptibility Panels Using Next-Generation Sequencing

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Select a hyperlink below to be directed to that section.

**POLICY CRITERIA | CODING | RELATED INFORMATION**

**EVIDENCE REVIEW | REFERENCES | HISTORY**

∞ Clicking this icon returns you to the hyperlinks menu above.

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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.

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**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.
### Test

<table>
<thead>
<tr>
<th>Expansed cancer molecular panels</th>
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</thead>
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The use of expanded cancer molecular panels for selecting targeted cancer treatment is considered investigational.

### Coding

<table>
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<tr>
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<th>Description</th>
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<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</td>
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<tr>
<td>0037U</td>
<td>Targeted genomic sequence analysis, solid organ neoplasm, DNA analysis of 324 genes, interrogation for sequence variants, gene copy number amplifications, gene rearrangements, microsatellite instability and tumor mutational burden</td>
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<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, PDGFRA, PDGFRB, PGR, PIK3CA, 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, or 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, 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</td>
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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

There is interest in treating cancers by targeting biologic pathways that are influenced 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. Some individual markers have established benefit in certain types of cancers; they are not addressed in this medical policy. Rather, this review focuses 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

Traditional Therapeutic Approaches to Cancer

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 of tumors are broadly categorized according to the tissue, organ, or body compartment in which they arise. 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, noting a low of 25% for cancer chemotherapeutics, 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.

**Targeted Cancer Therapy**

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. The use of genetic markers allows cancers to be further classified by “pathways” defined at the molecular level. An expanding number of genetic markers have been identified. Dienstmann et al (2013) categorized these markers into 3 classes: (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 small number of individual genetic markers fall into the first category (ie, have established utility for a particular cancer type). The utility of these markers has 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
  o RAS variants (KRAS, NRAS)
  o BRAF c1799T>A

• Non-small-cell lung cancer (NSCLC)
  o EGFR
  o ALK/ROS1
  o KRAS
  o RET
  o MET

• Metastatic melanoma
  o BRAF v600
  o C-KIT

• Ovarian cancer
  o BRCA (germline)

• Chronic myeloid leukemia
  o BRC-ABL

• Gastrointestinal stromal tumors
  o C-KIT

Testing for these individual variants with established utility is not addressed 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 NSCLC). This policy is also not intended to address the use of these cancer-specific panels that include a few variants. Rather, the intent is to address expanded panels that test for many potential variants that do not have established efficacy for the specific cancer in question.

When advanced cancers are tested with expanded molecular panels, most patients are found to have at least 1 potentially pathogenic variant.4-6 The number of variants varies widely by types of cancers, different variants 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. The 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 variant among cancers that originate from different organs. There are several examples of variant-directed treatment that was effective in 1 type of cancer but ineffective in another. For example, targeted therapy for epidermal growth factor receptor (EGFR) variants has been successful in NSCLC but not in trials of other cancer types. Treatment with tyrosine kinase inhibitors based on variant 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 variant are treated with a targeted agent, also have been performed. One such study was published in 2015 by Hyman et al. In this study, 122 patients with BRAF V600 variants 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 Molecular Panels**

*Table 1* provides a select list of commercially available expanded cancer molecular panels.

**Table 1. Commercially Available Molecular Panels for Solid and Hematologic Tumor Testing**

<table>
<thead>
<tr>
<th>Test (Manufacturer)</th>
<th>Tumor Type</th>
<th>No. of Genes Tested</th>
<th>Technology</th>
</tr>
</thead>
<tbody>
<tr>
<td>FoundationOne® test (Foundation Medicine, Cambridge, MA)&lt;sup&gt;9&lt;/sup&gt;</td>
<td>Solid</td>
<td>315 cancer-related genes and introns from 28 genes</td>
<td>NGS</td>
</tr>
<tr>
<td>FoundationOne® Heme test (Foundation Medicine, Cambridge, MA)&lt;sup&gt;9&lt;/sup&gt;</td>
<td>Hematologic</td>
<td>406 cancer-related genes and selected introns from 31 genes involved in rearrangements</td>
<td>RNA sequencing</td>
</tr>
<tr>
<td>OnkoMatch™ (GenPath Diagnostics, Elmwood Park, NJ)&lt;sup&gt;10&lt;/sup&gt;</td>
<td>Solid</td>
<td>68 variants in 14 oncogenes and tumor suppressor genes</td>
<td>Multiplex PCR</td>
</tr>
<tr>
<td>Test (Manufacturer)</td>
<td>Tumor Type</td>
<td>No. of Genes Tested</td>
<td>Technology</td>
</tr>
<tr>
<td>--------------------</td>
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<td>---------------------</td>
<td>------------</td>
</tr>
<tr>
<td>GeneTrails® Solid Tumor Panel (Knight Diagnostic Labs, Portland, OR)</td>
<td>Solid</td>
<td>123 genes</td>
<td></td>
</tr>
<tr>
<td>Tumor profiling service (Caris Molecular Intelligence through Caris Life Sciences, Irving, TX)</td>
<td>Solid</td>
<td>Up to 56 tumor-associated genes</td>
<td>NGS, IHC, FISH, Sanger sequencing, pyrosequencing, quantitative PCR, fragmentation analysis</td>
</tr>
<tr>
<td>SmartGenomics™ (PathGroup, Nashville, TN)</td>
<td>Solid and hematologic</td>
<td>160 genes and 126 gene fusions</td>
<td>NGS, cytogenomic array, other technologies</td>
</tr>
<tr>
<td>Guardant360 panel (GuardantHealth, Redwood City, CA)</td>
<td>Solid</td>
<td></td>
<td>Digital sequencing</td>
</tr>
<tr>
<td>Paradigm Cancer Diagnostic (PcDx™) Panel (Paradigm, Phoenix, AZ)</td>
<td>Solid</td>
<td>186 alterations</td>
<td>NGS</td>
</tr>
<tr>
<td>Memoral Sloan Kettering-Integrated Mutation Profiling of Actionable Cancer Targets (MSK-IMPACT™; Memorial Sloan Kettering Cancer Center, New York, NY)</td>
<td>Solid</td>
<td>341 cancer-associated genes</td>
<td>NGS</td>
</tr>
<tr>
<td>TruSeq® Amplicon Panel (Illumina, San Diego, CA)</td>
<td>Solid</td>
<td>48 cancer-related genes</td>
<td>NGS</td>
</tr>
<tr>
<td>Illumina TruSight™ Tumor (Illumina, San Diego, CA)</td>
<td>Solid</td>
<td>26 cancer-related genes</td>
<td>NGS</td>
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<tr>
<td>Ion AmpliSeq™ Comprehensive Cancer Panel (Thermo Fisher Scientific, Waltham, MA)</td>
<td>Solid</td>
<td>&gt;400 cancer-related genes and tumor suppressor genes</td>
<td>NGS</td>
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<tr>
<td>Ion AmpliSeq™ Cancer Hotspot Panel v2 (Thermo Fisher Scientific, Waltham, MA)</td>
<td>Solid</td>
<td>“Hotspot” regions of 50 cancer-related and tumor suppressor genes</td>
<td>NGS</td>
</tr>
</tbody>
</table>

FISH: fluorescence in situ hybridization; IHC: immunohistochemistry; NGS: next-generation sequencing; PCR: polymerase chain reaction.
Summary of Evidence

For individuals who have cancers that have not responded to standard therapy and whose tumors were tested with an expanded cancer molecular panel, the evidence includes a randomized controlled trial, 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 variants for particular types of cancer is not easily obtained from the available published literature. The large number of variants and many different types of cancer preclude determination of clinical validity for the panels as a whole. Some evidence has reported that many of the identified variants are false positives (ie, not biologically active), after filtering by comparison with matched normal tissue and cancer variant databases. To demonstrate clinical utility, direct evidence from interventional trials, ideally randomized controlled trials, are needed that compare the strategy of targeted treatment based on panel results with standard care. The first such published randomized controlled trial (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 nonmatched 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. Also, 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.

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in Table 2.

Table 2. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
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<tr>
<td>Ongoing</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>NCT01891344</td>
<td>A Study of Rucaparib in Patients With Platinum-Sensitive, Relapsed, High-Grade Epithelial Ovarian,</td>
<td>480</td>
<td>Apr 2017</td>
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<tr>
<td>NCT No.</td>
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<td>Completion Date</td>
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<td>----------------------------------------------------------------------------</td>
<td>--------------------</td>
<td>-----------------</td>
</tr>
<tr>
<td>NCT01987726</td>
<td>Comprehensive Gene Sequencing in Guiding Treatment Recommendations Patients With Metastatic or Recurrent Solid Tumors</td>
<td>150</td>
<td>Dec 2017</td>
</tr>
<tr>
<td>NCT01939847</td>
<td>IMAGE Study: Personalized Molecular Profiling in Cancer Treatment at Johns Hopkins</td>
<td>96</td>
<td>Jun 2018</td>
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<tr>
<td>NCT02693535</td>
<td>TAPUR: Testing the Use of Food and Drug Administration (FDA) Approved Drugs That Target a Specific Abnormality in a Tumor Gene in People With Advanced Stage Cancer (TAPUR)</td>
<td>1060</td>
<td>Mar 2019</td>
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<tr>
<td>NCT02152254</td>
<td>Randomized Study Evaluating Molecular Profiling and Targeted Agents in Metastatic Cancer: Initiative for Molecular Profiling and Advanced Cancer Therapy (IMPACT 2)</td>
<td>1362</td>
<td>May 2019</td>
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<tr>
<td>NCT02437617</td>
<td>Genomic Profiling Assay in Phase</td>
<td>300</td>
<td>Jul 2019</td>
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<tr>
<td>NCT02029001</td>
<td>Adapting Treatment to the Tumor Molecular Alterations for Patients with Advanced Solid Tumors: My Own Specific Treatment</td>
<td>560</td>
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<tr>
<td>NCT02299999</td>
<td>Evaluation of the Efficacy of High Throughput Genome Analysis as a Therapeutic Decision Tool for Patients with Metastatic Breast Cancer (SAFIR02_Breast)</td>
<td>1460</td>
<td>Jun 2021</td>
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<td>NCT02645149</td>
<td>Molecular Profiling and Matched Targeted Therapy for Patients With Metastatic Melanoma</td>
<td>1000</td>
<td>Jun 2021</td>
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<tr>
<td>NCT02465060</td>
<td>Molecular Analysis for Therapy Choice (MATCH)</td>
<td>6452</td>
<td>Jun 2022</td>
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<tr>
<td>NCT02154490</td>
<td>A Biomarker-Driven Master Protocol for Previously Treated Squamous Cell Lung Cancer (Lung-MAP)</td>
<td>10000</td>
<td>Apr 2025</td>
</tr>
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</table>

NCT: national clinical trial
* Denotes industry-sponsored or cosponsored trial

Practice Guidelines and Position Statements

National Comprehensive Cancer Network (NCCN)

The National Comprehensive Cancer Network guidelines do not contain recommendations for the general strategy of testing a tumor for a wide range of variants. 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 below:

- **Breast cancer**\(^{29}\)
  - HER2 testing, when specific criteria are met

- **Colon cancer**\(^{30}\)
  - KRAS, NRAS, and BRAF testing for patients with metastatic colon cancer

- **Non-small-cell lung cancer**\(^{31}\)
  - 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
  - Strongly endorses broader molecular profiling to identify rare driver mutations (HER2, BRAF V600E, ROS1, and RET gene rearrangements, and MET amplification or MET exon skipping)

- **Melanoma**\(^{32}\)
  - BRAF V600 testing for patients with metastatic disease
  - Activating C-KIT variants for patients with metastatic disease

- **Ovarian cancer**\(^{33}\)
  - BRCA

- **Chronic myelogenous leukemia**\(^{34}\)
  - BCR-ACL

- **Gastrointestinal stromal tumors**\(^{35}\)
  - C-KIT

- **Bladder cancer**\(^{36,37}\)
  - Comprehensive molecular profiling for advanced 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 must meet the general regulatory standards of the Clinical Laboratory Improvement Amendments. Laboratories that offer laboratory-developed tests must be licensed by the Clinical Laboratory Improvement Amendments 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


### History

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<tr>
<th>Date</th>
<th>Comments</th>
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<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>
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<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>
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<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>
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| 12/08/15   | 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
<table>
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<tr>
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<td>Update related policies. 12.04.92 was deleted and replaced with 12.04.520.</td>
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<td>06/24/16</td>
<td>Minor update. Removed 81210 from list of examples in the Coding section.</td>
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<td>08/01/16</td>
<td>Coding update. Added CPT codes 81445, 81450, and 81455.</td>
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<td>01/01/17</td>
<td>Updated Related Policies, removed 12.04.520 as it was archived.</td>
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<tr>
<td>07/07/17</td>
<td>Policy moved into new format, no changes to policy statement.</td>
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<tr>
<td>10/06/17</td>
<td>Coding update; added new CPT code 0017U, effective 8/1/17.</td>
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<tr>
<td>05/19/18</td>
<td>Coding update, added CPT code 0037U.</td>
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U.S. Department of Health and Human Services
200 Independence Avenue SW, Room S09F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)
Complaint forms are available at:

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Tagalog (Tagalog):

ไทย (Thai):
ประกาศนี้มีข้อมูลที่สำคัญเกี่ยวกับการขอความช่วยเหลือประกันสุขภาพของคุณ Premera Blue Cross และรายละเอียดในการชำระเงินค่าใช้จ่ายของคุณ คุณควรจดจำข้อมูลในการถวายสิทธิ์ที่ชัดเจนและระยะเวลาที่แน่นอนเพื่อให้บริษัทประกันสุขภาพของคุณสามารถเข้าใจว่ามีใครจะได้รับการช่วยเหลือและรายละเอียดเพิ่มเติมในกรณีการไม่ได้จ่าย โทรศัพท์ 800-722-1471 (TTY: 800-842-5357).

Русский (Russian):
Настоящее уведомление содержит важную информацию. Это уведомление может содержать важную информацию о вашем заявлении или страховом покрытии через Premera Blue Cross. В настоящем уведомлении могут быть указаны ключевые даты. Вам, возможно, потребуется принять меры к определенным предельным срокам для сохранения страхового покрытия или помощи с расходами. Вы имеете право на бесплатное получение этой информации и помощь на вашем языке. Звоните по телефону 800-722-1471 (TTY: 800-842-5357).

Романский (Romanian):

日本語 (Japanese):
この通知には重要な情報が含まれています。この通知は、Premera Blue Crossの申請または補償範囲に関する重要な情報が含まれていることがあります。この通知に記載されている情報が重要である場合を除き、健康保険料や除外事項を維持するには、特定の期限までに行動を取られる必要がある場合があります。ご注文による情報を何そうではない場合があります。800-722-1471 (TTY: 800-842-5357)までお電話ください。

한국어 (Korean):
본 통지서에는 중요한 정보가 들어 있습니다. 즉 이 통지서는 귀하의 신청에 관한 Premera Blue Cross을 통한 커버리지에 관한 정보를 포함하고 있는 것입니다. 본 통지서에는 빠짐없이 있는 날짜들이 있을 수 있습니다. 귀하는 귀하의 신청 커버리지를 계속 유지하거나 비용을 절감하기 위해서 일정한 마감일까지 조치를 취해야 할 필요가 있을 수 있습니다. 귀하는 이러한 정보와 도움을 귀하의 언어에 비용 부담없이 얻을 수 있는 권리가 있습니다. 800-722-1471 (TTY: 800-842-5357)로 전화하십시오.