

(20492)

<b>Medical Benefit</b>		<b>Effective Date:</b> 01/01/17	<b>Next Review Date:</b> 09/17
<b>Preauthorization</b>	Yes	<b>Review Dates:</b> 09/13, 09/14, 09/15, 09/16	

***Preauthorization is required.***

*The following Protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient’s contract at the time the services are rendered.*

**Description**

Genetic panel testing offers potential advantages and disadvantages compared with direct sequence analysis. This conceptual framework outlines a structure for evaluating the utility of genetic panels, by classifying them into clinically relevant categories and developing criteria for evaluating panels in each category.

**Summary of Evidence**

Genetic panels using next-generation technology or chromosomal microarray analysis are available for many clinical conditions. The major advantage of panels is the ability to analyze many genes simultaneously, potentially improving the breadth and efficiency of genetic workup. A potential disadvantage of panels is that they provide a large amount of ancillary information whose significance may be uncertain. Limited published evidence reports that the analytic validity of panels approaches that of direct sequencing. The clinical validity and clinical utility of panels are condition-specific. The clinical validity of panels will reflect the clinical validity of the underlying individual mutations. The clinical utility of panels will depend on the context in which they are used, i.e., whether the advantages of panel testing outweigh the disadvantages for the specific condition under consideration.

Panels can be classified into categories based on their intended use and composition. For each category of panels, specific criteria can be used to evaluate medical necessity. When all criteria for a given category are met, that panel may be considered medically necessary.

**Policy**

Genetic panels that use next generation sequencing or chromosomal microarray analysis, and are classified in one of the categories below, may be considered **medically necessary** when all criteria are met for each category, as outlined in the Policy Guidelines Section:

- Panels for hereditary or genetic conditions
  - Diagnostic testing of an individual’s germline to benefit the individual
  - Testing of an asymptomatic individual to determine future risk of disease
- Cancer panels

- Testing of an asymptomatic individual to determine future risk of cancer
- Testing cancer cells from an individual to benefit the individual by identifying targeted treatment
- Reproductive panels
  - Preconception testing
    - Carrier testing of the parent(s)
  - Prenatal testing
    - Carrier testing of the parent(s)
    - In utero testing of a fetus, including testing for aneuploidy or mutations
  - Preimplantation genetic testing.

Genetic panels that use next generation sequencing or chromosomal microarray analysis that do not meet the criteria for a specific category are considered **investigational**.

\*\*Refer to the Genetic Cancer Susceptibility Panels Using Next Generation Sequencing Protocol for the following panels: CancerNext™, BreastNext™, ColoNext™, and OvaNext™

## Policy Guidelines

### *Criteria for Evaluating Genetic Panels*

The following are all criteria that can be applied to evaluating genetic panels, with an explanation of the way the criteria are to be defined and applied. Not all criteria will apply to all panels.

#### Test is performed in a Clinical Laboratory Improvement Amendment (CLIA)-licensed lab

- Testing is performed in a laboratory licensed under CLIA for high-complexity testing. This requires delivery of a reproducible set of called, quality filtered variants from the sequencing platform.
- These calculations should occur prior to variant annotation, filtering, and manual interpretation for patient diagnosis.

#### Analytic validity of panels approaches that of direct sequencing

- The analytic validity for detecting individual mutations, compared with the criterion standard of conventional direct Sanger sequencing, is reported.
  - The testing methods are clearly described, and the overall analytic validity for that type of testing is defined.
- Any decrease in analytic sensitivity and specificity is not large enough to result in a clinically meaningful difference in diagnostic accuracy (clinical validity).

All individual components of the panel have demonstrated clinical utility for the condition being evaluated OR the implications and consequences of test results that have not demonstrated clinical utility are clear and there is not a potential for incidental findings to cause harm.

- For each panel, if each mutation in the panel would be indicated for at least some patients with the condition, then the criterion is met.
  - If there are individual mutations that do not have clinical utility, then the potential to cause harm might occur

- For incidental findings, the potential for harm may be due to:
  - Incorrect diagnosis due to false positive or false negative results
    - False positive - Unnecessary treatment that may have adverse effects
    - False negative - Effective treatment not provided
  - Incorrect risk assessment
    - Unnecessary surveillance tests that may lead to further confirmatory tests that may be invasive
    - Effective surveillance/screening not provided to patients at risk
    - Incorrect decision made on reproductive decision making
      - Alteration made in reproductive planning that would not have been made with correct information
      - No alteration made in reproductive planning, where alteration would have been made with correct information

Panel testing offers substantial advantages in efficiency compared to sequential analysis of individual genes

- The composition of the panel is sufficiently complex such that next generation sequencing, or chromosomal microarray, is expected to offer considerable advantages. Complexity of testing can be judge by:
  - The number of genes tested.
  - The size of the genes tested.
  - The heterogeneity of the genes tested.

The impact of ancillary information is well-defined

- If a panel contains both mutations that are medically necessary and mutations that are investigational (or not medically necessary), the impact of results for investigational (or not medically necessary) mutations is considered, taking into account the following possibilities:
  - The information may be ignored (no further impact).
  - The information may result in further testing or changes in management.
    - Positive impact
    - Negative impact
  - It is more likely that the results of tests that are not medically necessary cause a negative, rather than a positive, impact on the patient. This is because additional tests and management changes that follow are not evidence-based, and because additional testing and treatment generally involves risks.

Decision making based on genetic results is well-defined

- Results of genetic test will lead to changes in diagnosis and/or treatment.
- The potential changes in treatment are defined prior to testing and are in accordance with current standard of care.
- Changes in diagnosis or management are associated with improvements in health outcomes.
- For prenatal and preconception testing:
  - Alterations in reproductive decision making are expected, depending on the results of testing.

### Yield of testing is acceptable for the target population

- The number of individuals who are found to have a pathologic mutation, in relation to the total number of individuals tested, is reasonable given the underlying prevalence and severity of the disorder, and the specific population that is being tested.
  - It is not possible to set an absolute threshold for acceptable yield across different clinical situations. Some guidance can be given from clinical precedence as follows:
    1. For diagnosis of hereditary disorders, genetic testing is generally performed when signs and symptoms of disease are present, including family history. The likelihood of a positive genetic test depends on the accuracy of the signs and symptoms (pre-test probability of disorder), and the clinical sensitivity of genetic testing. For disorders such as testing for congenital long QT syndrome and Duchenne muscular dystrophy, the likelihood of a positive result in patients with signs and symptoms of disease is greater than 10%.
    2. For cancer susceptibility, testing is recommended for genetic abnormalities such as BRCA and Lynch syndrome when the likelihood of a positive result is in the range of 2% to 10%.
    3. For a clinical syndrome that has multiple underlying etiologies, such as developmental delay in children, chromosomal microarray testing is recommended when the likelihood of a positive result is in the 5% to 20% range.
- There is Increase in yield over alternate methods of diagnosis, and this increase is clinically significant.

### Other issues to consider

- Most tests will not, and possibly should not, be ordered by generalists.
  - Guidance for providers is appropriate on the expertise necessary to ensure that test ordering is done in optimal fashion.
- Many tests, particularly those for inherited disorders, should be accompanied by patient counseling, preferably by certified genetic counselors.
  - Counseling may be needed both before and after testing, depending on the specific condition being tested.

### Criteria for Evaluating Panels by Type and Intent of Panel

Panel Category	Examples of Panels	Criteria for Evaluating Utility of Panel
<b>1. Diagnosis of hereditary, single-gene disorders</b>		<ul style="list-style-type: none"> <li>• All individual components of the panel have demonstrated clinical utility OR test results that have not demonstrated clinical utility do not have a potential to cause harm</li> <li>• Testing is performed in a CLIA-approved lab</li> <li>• Analytic validity of panel approaches that of direct sequencing</li> <li>• Panel testing offers substantial advantages in efficiency compared to sequential analysis of individual genes</li> </ul>
<b>Category 1a – Diagnostic testing</b> Panels that include mutations for a single condition	<ul style="list-style-type: none"> <li>• Retinitis Pigmentosa Panel</li> <li>• Leigh Disease Panel</li> </ul>	<ul style="list-style-type: none"> <li>• Includes all criteria for criterion 1, Diagnosis of hereditary, single-gene disorders</li> </ul>
<b>Category 1b – Diagnostic testing</b> Panels that include mutations for	<ul style="list-style-type: none"> <li>• Retinitis Pigmentosa/Leber Congenital Amaurosis Panel</li> </ul>	<ul style="list-style-type: none"> <li>• Includes all criteria for criterion 1, Diagnosis of hereditary, single-gene disorders PLUS</li> </ul>

Panel Category	Examples of Panels	Criteria for Evaluating Utility of Panel
multiple conditions (indicated plus non-indicated conditions)	<ul style="list-style-type: none"> <li>• Pan Cardio Panel</li> <li>• Noonan Syndrome and Related Disorders Panel</li> </ul>	<ul style="list-style-type: none"> <li>• The impact of ancillary information is well-defined.</li> </ul>
<b>Category 1c – Diagnostic testing</b> Panels that include mutations for multiple conditions (clinical syndrome for which clinical diagnosis not possible)	<ul style="list-style-type: none"> <li>• X-linked Intellectual Disability Panel</li> <li>• Marfan, Aneurysm and Related Disorders Panel</li> <li>• Epilepsy Panel</li> </ul>	<ul style="list-style-type: none"> <li>• Includes all criteria for criterion 1, Diagnosis of hereditary, single-gene disorders PLUS</li> <li>• The impact of ancillary information is well-defined</li> <li>• Yield of testing is acceptable for the target population</li> </ul>
<b>Category 1d – Risk Assessment</b> Risk assessment panels for at-risk individuals	<ul style="list-style-type: none"> <li>• Most panels for hereditary conditions can be used for this purpose when there is not a known mutation in the family</li> </ul>	<ul style="list-style-type: none"> <li>• Includes all criteria for criterion 1, Diagnosis of hereditary, single-gene disorders PLUS</li> <li>• Yield of testing is acceptable for the target population.</li> </ul>
<b>2. Cancer panels</b>		<ul style="list-style-type: none"> <li>• All individual components of the panel have demonstrated clinical utility, OR test results that have not demonstrated clinical utility do not have a potential to cause harm</li> <li>• Testing is performed in a CLIA-approved lab</li> <li>• Analytic validity of panel approaches that of direct sequencing</li> <li>• Panel testing offers substantial advantages in efficiency compared with sequential analysis of individual genes</li> </ul>
<b>Category 2a – Risk assessment</b> Risk assessment panels for at-risk individuals	<ul style="list-style-type: none"> <li>• Hereditary colon cancer syndromes panel</li> <li>• BreastNext Panel</li> </ul>	<ul style="list-style-type: none"> <li>• Includes all criteria for criterion 2, Cancer panels PLUS</li> <li>• Yield of testing is acceptable for the target population.</li> </ul>
<b>Category 2b – Targeted treatment based on mutation analysis</b> <ul style="list-style-type: none"> <li>• Panels with multiple mutations intended to direct treatment – all indicated tests</li> <li>• Effective targeted treatment based on mutation analysis is available</li> </ul>	<ul style="list-style-type: none"> <li>• None identified</li> </ul>	<ul style="list-style-type: none"> <li>• Includes all criteria for criterion 2, Cancer panels PLUS</li> <li>• Yield of testing is acceptable for the target population.</li> </ul>
<b>Category 2c – Targeted treatment based on mutation analysis</b> <ul style="list-style-type: none"> <li>• Panels with multiple mutations intended to direct treatment (indicated plus non-indicated tests)</li> <li>• Effective targeted treatment based on mutation analysis has not been established</li> </ul>	<ul style="list-style-type: none"> <li>• CancerNext panels, when there is an effective targeted treatment for the specific type of cancer</li> </ul>	<ul style="list-style-type: none"> <li>• Includes all criteria for criterion 2, Cancer panels PLUS</li> <li>• Impact of ancillary information is defined.</li> </ul>
<b>Category 2d</b> <ul style="list-style-type: none"> <li>• Panels with multiple mutations intended to direct treatment – no indicated tests for that particular cancer</li> </ul>	<ul style="list-style-type: none"> <li>• CancerNext panels, when there is no known effective treatment for the specific type of cancer</li> </ul>	<ul style="list-style-type: none"> <li>• Includes all criteria for criterion 2, Cancer panels PLUS</li> <li>• Decision-making based on potential results is defined</li> <li>• Yield of testing is acceptable for the target</li> </ul>

Panel Category	Examples of Panels	Criteria for Evaluating Utility of Panel
<ul style="list-style-type: none"> <li>Effective targeted treatment based on mutation analysis has not been established</li> </ul>		<p>population</p> <ul style="list-style-type: none"> <li>Impact of ancillary information is defined</li> <li>Probability that ancillary information leads to further testing or management changes</li> </ul>
<b>3. Reproductive panels</b>		<ul style="list-style-type: none"> <li>All individual components of the panel have demonstrated clinical utility, OR test results that have not demonstrated clinical utility do not have a potential to cause harm</li> <li>Testing is performed in a CLIA-approved lab</li> <li>Analytic validity of panel approaches that of direct sequencing</li> <li>Panel testing offers substantial advantages in efficiency compared to sequential analysis of individual genes</li> </ul>
<p><b>Category 3a – Preconception testing of at-risk individuals</b> Panels that include only mutations associated with increased risk</p>	<ul style="list-style-type: none"> <li>Ashkenazi Jewish Carrier Test Panel</li> <li>GoodStart Panel (customized)</li> </ul>	<ul style="list-style-type: none"> <li>Includes all criteria for criterion 3, Reproductive panels PLUS</li> <li>Decision-making based on genetic results is well-defined</li> </ul>
<p><b>Category 3b – Preconception testing of at-risk individuals</b> Panels that include mutations associated with increased risk plus other mutations</p>	<ul style="list-style-type: none"> <li>GoodStart Panel (full panel, not customized)</li> </ul>	<ul style="list-style-type: none"> <li>Includes all criteria for criterion 3. Reproductive panels PLUS</li> <li>Decision-making based on genetic results is well-defined</li> <li>Impact of ancillary information is defined</li> </ul>
<p><b>Category 3c – Preconception screening</b> Panels intended for preconception testing – screening panels for different populations</p>	<ul style="list-style-type: none"> <li>Counsyl Panel</li> </ul>	<ul style="list-style-type: none"> <li>Includes all criteria for criterion 3, Reproductive panels PLUS</li> <li>Yield of testing is acceptable for the target population</li> <li>Decision-making based on genetic results is well-defined</li> </ul>
<p><b>Category 3d – Prenatal screening</b> Panels that include only mutations associated with increased risk</p>	<ul style="list-style-type: none"> <li>Signature Prenatal Microarray Panel (customized)</li> </ul>	<ul style="list-style-type: none"> <li>Includes all criteria for criterion 3, Reproductive panels PLUS</li> <li>Decision-making based on genetic results is well-defined</li> </ul>
<p><b>Category 3e – Prenatal screening</b> Panels that include mutations associated with increased risk plus other mutations</p>	<ul style="list-style-type: none"> <li>Signature Prenatal Microarray Panel (full panel, not customized)</li> </ul>	<ul style="list-style-type: none"> <li>Includes all criteria for criterion 3, Reproductive panels PLUS</li> <li>Yield of testing is acceptable for the target population</li> <li>Decision-making based on genetic results is well-defined</li> </ul>
<p><b>Category 3f – Preimplantation testing</b> Panels that include only mutations associated with increased risk</p>	<ul style="list-style-type: none"> <li>Signature Prenatal Microarray Panel (customized)</li> </ul>	<ul style="list-style-type: none"> <li>Includes all criteria for criterion 3, Reproductive panels PLUS</li> <li>Decision-making based on genetic results is well-defined</li> </ul>
<p><b>Category 3g – Preimplantation testing</b> Panels that include mutations associated with increased risk plus other mutations</p>	<ul style="list-style-type: none"> <li>Signature Prenatal Microarray Panel (full panel, not customized)</li> </ul>	<ul style="list-style-type: none"> <li>Includes all criteria for criterion 3, Reproductive panels PLUS</li> <li>Yield of testing is acceptable for the target population</li> </ul>

## Panel Category

## Examples of Panels

## Criteria for Evaluating Utility of Panel

- Decision-making based on genetic results is well-defined

### Medicare Advantage

Medicare generally only covers tests that are medically necessary for diagnosis and treatment, panels that are risk assessment testing may be considered **not medically necessary**.

The above policy and policy guidelines content is applicable for Medicare Advantage for diagnostic testing, prognostic testing and testing for genetic variants that alter response to treatment or to an environmental factor which meet medically necessary criteria.

### Background

This conceptual framework applies only if there is not a separate Protocol that outlines specific criteria for testing. If a separate Protocol does exist, then the criteria for medical necessity therein supersede the guidelines herein.

#### *Purpose*

The purpose of this conceptual framework is to provide a structure for evaluating the utility of genetic panels that use newer genetic testing methodologies. In providing a framework for evaluating genetic panels, this review will not attempt to determine the clinical utility of genetic testing for specific disorders per se. For most situations, this will mean that at least one mutation in the panel has already been determined to have clinical utility and that clinical indications for testing are established. Once the clinical utility for at least one of the mutations included in the panel has been established, then the focus is on whether use of a panel is a reasonable alternative to individual tests.

#### *Definition of a Genetic Panel*

A genetic panel will be defined as a test that simultaneously evaluates multiple genes, as opposed to sequential testing of individual genes. This includes panels performed by next-generation sequencing (NGS), massive parallel sequencing, and chromosomal microarray analysis (CMA) testing. The definition of a panel will not include panels that report on gene expression profiling, which generally do not directly evaluate genetic mutations.

#### *Background*

New genetic technology, such as NGS and CMA, has led to the ability to examine many genes simultaneously.<sup>1</sup> This in turn has resulted in a proliferation of genetic panels. Panels using next-generation technology are currently widely available, covering a broad range of conditions related to inherited disorders, cancer, and reproductive testing.<sup>2-4</sup> These panels are intuitively attractive to use in clinical care because they can analyze multiple genes more quickly and may lead to greater efficiency in the workup of genetic disorders. It is also possible that newer technology can be performed more cheaply than direct sequencing, although this may not be true in all cases.

Newer sequencing techniques were initially associated with higher error rates than direct sequencing.<sup>5</sup> While there are limited published data directly comparing the accuracy of NGS with direct sequencing, several publications in 2015 reported that the concordance between NGS and Sanger sequencing was greater than 99% for cancer susceptibility testing,<sup>6</sup> inherited disorders,<sup>7</sup> and hereditary hearing loss.<sup>8</sup> Another potential pitfall is the easy availability of a multitude of genetic information, much of which has uncertain clinical consequences.



Variants of unknown significance are found commonly and in greater numbers with NGS than with direct sequencing.<sup>9,10</sup>

The intended use for these panels is variable. For example, for the diagnosis of hereditary disorders, a clinical diagnosis may be already established, and genetic testing is performed to determine whether this is a hereditary condition, and/or to determine the specific mutation present. In other cases, there is a clinical syndrome (phenotype) with a broad number of potential diagnoses, and genetic testing is used to make a specific diagnosis. For cancer panels, there are also different intended uses. Some panels may be intended to determine whether a known cancer is part of a hereditary cancer syndrome. Other panels may include somatic mutations in a tumor biopsy specimen that may help identify a cancer type or subtype and/or help select best treatment.

There is no standardization to the makeup of genetic panels. Panel composition is variable, and different commercial products for the same condition may test a different set of genes. The makeup of the panels is determined by the specific lab that developed the test. In addition, the composition of any individual panel is likely to change over time, as new mutations are discovered and added to existing panels.

Despite the variability in the intended use and composition of panels, there are a finite number of broad panel types that can be identified and categorized. Once categorized, specific criteria on the utility of the panel can be developed for each category. One difficulty with this approach is that the distinction between the different categories, and the distinction between the intended uses of the panels, may not be clear. Some panels will have features or intended uses that overlap among the different categories.

To determine the criteria useful for evaluating panels, the evidence review will first classify panels into a number of clinically relevant categories, according to their intended use. Then, for each category, criteria will be proposed that can be applied to tests within that category. Because our goal is to outline a general approach to testing, we will not evaluate individual panels; rather, we will supply examples of genetic panels in each category to assist Plans in classifying the individual panels.

### 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 Amendments (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.

An exhaustive list of commercially available panel tests is beyond the scope of this conceptual framework. For example, one laboratory (Emory Genetics Laboratory) offers 243 different genetic panels, of a total of 929 molecular genetics tests.<sup>11</sup> Table 1 provides a sample of panels that use next-generation sequencing or chromosomal microarray analysis.

Table 1. Panels Using Next-Generation Sequencing or Chromosomal Microarray Analysis (as of February 2016)

Test Name	Laboratory
Agammaglobulinemia Panel	ARUP Laboratories
Ashkenazi Jewish Diseases Panel	ARUP Laboratories
Mitochondrial Disorders Panel	ARUP Laboratories
Amyotrophic Lateral Sclerosis Panel	ARUP Laboratories
Aortopathy Panel	ARUP Laboratories
Autism Panel	ARUP Laboratories
Brugada Syndrome Panel	ARUP Laboratories
Vascular Malformation Syndromes	ARUP Laboratories



Test Name	Laboratory
Retinitis Pigmentosa/Leber Congenital Amaurosis Panel	ARUP Laboratories
Cardiomyopathy and Arrhythmia Panel	ARUP Laboratories
Periodic Fever Syndromes Panel	ARUP Laboratories
Arrhythmias Sequencing Panel	Emory Genetics Laboratory
Arrhythmias Deletion/Duplication Panel	Emory Genetics Laboratory
Autism Spectrum Disorders	Emory Genetics Laboratory
Cardiomyopathy Panel	Emory Genetics Laboratory
Ciliopathies Panel	Emory Genetics Laboratory
Congenital Glycosylation Disorders	Emory Genetics Laboratory
ACOG/ACMG Carrier Screen Targeted Mutation Panel	Emory Genetics Laboratory
Epilepsy	Emory Genetics Laboratory
Eye Disorders	Emory Genetics Laboratory
Neuromuscular Disorders	Emory Genetics Laboratory
Noonan Syndrome and Related Disorders	Emory Genetics Laboratory
Short Stature Panel	Emory Genetics Laboratory
Sudden Cardiac Arrest Panel	Emory Genetics Laboratory
X-linked Intellectual Disability	Emory Genetics Laboratory
CancerNext™	Ambry Genetics
BreastNext™	Ambry Genetics
ColoNext™	Ambry Genetics
OvaNext™	Ambry Genetics
Pan Cardio Panel	Ambry Genetics
X-linked Intellectual Disability	Ambry Genetics
Marfan, Aneurysm and Related Disorders Panel	Ambry Genetics
Cobalamin Metabolism Comprehensive Panel	Baylor College of Medicine
Progressive External Ophthalmoplegia Panel	Baylor College of Medicine
CoQ10 Comprehensive Panel	Baylor College of Medicine
Usher Syndrome Panel	Baylor College of Medicine
Retinitis Pigmentosa Panel	Baylor College of Medicine
Pyruvate Dehydrogenase Deficiency and Mitochondrial Respiratory Chain Complex V Deficiency Panel	Baylor College of Medicine
Myopathy/Rhabdomyolysis Panel	Baylor College of Medicine
Mitochondrial Disorders Panel	Baylor College of Medicine
Low Bone Mass Panel	Baylor College of Medicine
Glycogen Storage Disorders Panel	Baylor College of Medicine
Leigh Disease Panel	Medical Neurogenetics
Pan Cardiomyopathy Panel	Partners Healthcare
Isolated Non-syndromic Congenital Heart Defects Panel	Partners Healthcare
Noonan Spectrum Panel	Partners Healthcare
Usher Syndrome Panel	Partners Healthcare
Hereditary Colon Cancer Syndromes	Mayo Medical Laboratories
Hypertrophic Cardiomyopathy Panel	Mayo Medical Laboratories
Dilated Cardiomyopathy Panel	Mayo Medical Laboratories
Arrhythmogenic Right Ventricular Cardiomyopathy Panel	Mayo Medical Laboratories

Test Name	Laboratory
Noonan Syndrome Panel	Mayo Medical Laboratories
Marfan Syndrome Panel	Mayo Medical Laboratories
Long QT Syndrome	Mayo Medical Laboratories
Brugada Syndrome	Mayo Medical Laboratories
Signature Prenatal Microarray	Signature Genomics
Counsyl™ Panel	Counsyl Genomics
GoodStart Select™	GoodStart Genetics

### Related Protocols

Expanded Molecular Panel Testing of Cancers to Identify Targeted Therapies

General Approach to Genetic Testing

Genetic Cancer Susceptibility Panels Using Next- Generation Sequencing

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Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this Protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

### References

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

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12. National Government Services, Inc Local Coverage Determination (LCD): Molecular Pathology Procedures (L35000), Revision Effective Date for services performed on or after 04/01/2016.