Introduction

There are many genetic tests. High-quality medical studies show certain genetic tests are helpful when diagnosing some conditions or guiding treatment. However, not all genetic tests have been well studied. In some cases, studies have shown that genetic tests aren’t useful in making a diagnosis or changing care. This policy lists a number of genetic tests where there is not enough evidence in published medical studies to show that they bring health benefits. These tests are considered unproven.

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

<table>
<thead>
<tr>
<th>Test Name</th>
<th>Investigational</th>
</tr>
</thead>
<tbody>
<tr>
<td>Celiac PLUS</td>
<td>All of the tests listed in this policy are considered</td>
</tr>
<tr>
<td>Crohn Prognostic</td>
<td></td>
</tr>
</tbody>
</table>

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.
Test Name

- DecisionDx-Melanoma™
- DecisionDx-Thymoma
- DNA Methylation
- Pathway Profile
- GI Effects® (Stool)
- IBD sgi Diagnostic™
- ImmunoGenomic® Profile
- Know Error™
- ResponseDX®: Colon
- TransPredict Fc gamma 3A

Investigational

investigational and grouped according to the categories of genetic testing as outlined in Medical Policy 12.04.91 (General Approach to Genetic Testing; see Related Policies above):

- Testing of an affected (symptomatic) individual’s germline to benefit the individual (excluding reproductive testing)
- Diagnostic testing
- Prognostic testing
- Therapeutic testing

Testing an asymptomatic individual to determine future risk of disease genetic testing is considered investigational when criteria are not met, including when there is insufficient evidence to determine whether the technology improves health outcomes.

Note: See Table 1 in Evidence Review for additional information about test names listed at the left.

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**Coding**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT</td>
<td></td>
</tr>
<tr>
<td>81229</td>
<td>Cytogenomic constitutional (genome-wide) microarray analysis; interrogation of genomic regions for copy number and single nucleotide polymorphism (SNP) variants for chromosomal abnormalities</td>
</tr>
<tr>
<td>81407</td>
<td>Molecular pathology procedure, Level 8 (eg, analysis of 26-50 exons by DNA sequence analysis, mutation scanning or duplication/deletion variants of &gt;50 exons, sequence analysis of multiple genes on one platform)</td>
</tr>
<tr>
<td>81479</td>
<td>Unlisted molecular pathology procedure</td>
</tr>
<tr>
<td>84999</td>
<td>Unlisted chemistry procedure</td>
</tr>
</tbody>
</table>

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Description

There are numerous commercially available genetic and molecular diagnostic, prognostic, and therapeutic tests for individuals with certain diseases and tests of future risk in asymptomatic individuals. This medical policy evaluates miscellaneous genetic and molecular diagnostic tests not addressed in a separate review. If a separate medical policy exists, then conclusions reached there supersede conclusions in this policy. The main criterion for inclusion in this policy is the limited evidence on the clinical validity for the test. As a result, these tests do not have clinical utility and the evidence is insufficient to determine the effect on health outcomes. The lack of clinical utility of these tests is based on criteria outlined in a separate medical policy (see Related Policies).

Background

Tests that are assessed in this medical policy are listed in Table 1. Excluding reproductive testing, there are primarily three reasons why genetic and molecular tests might be useful to a person with a disease: diagnostic testing, prognostic testing, and therapeutic testing. A fourth reason would be testing that is done on an asymptomatic person to determine his/her future risk of developing the disease.

Table 1: Genetic and Molecular Diagnostic Tests in This Medical Policy

<table>
<thead>
<tr>
<th>Test Name</th>
<th>Manufacturer</th>
<th>Date Added</th>
<th>Diagnosis</th>
<th>Risk Assessment</th>
<th>Prognosis</th>
<th>Treatment Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Celiac PLUS</td>
<td>Prometheus</td>
<td>Oct 2014</td>
<td>•</td>
<td>•</td>
<td>•</td>
<td></td>
</tr>
<tr>
<td>Test Name</td>
<td>Manufacturer</td>
<td>Date Added</td>
<td>Diagnosis</td>
<td>Risk Assessment</td>
<td>Prognosis</td>
<td>Treatment Response</td>
</tr>
<tr>
<td>---------------------------</td>
<td>-----------------------------------</td>
<td>------------</td>
<td>---------------------</td>
<td>-----------------</td>
<td>-----------</td>
<td>--------------------</td>
</tr>
<tr>
<td>ColonSentry®</td>
<td>GeneNews®</td>
<td>Aug 2015</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Crohn’s Prognostic</td>
<td>Prometheus</td>
<td>Oct 2014</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DecisionDx-Melanoma™</td>
<td>Castle</td>
<td>Jan 2015</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DecisionDx-Thymoma</td>
<td>Castle</td>
<td>Jan 2015</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DNA Methylation Pathway Profile</td>
<td>Great Plains Laboratory</td>
<td>Jan 2015</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>GI Effects® (Stool)</td>
<td>Genova Dxcs</td>
<td>Jan 2015</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IBD sgi Diagnostic™</td>
<td>Prometheus</td>
<td>Oct 2014</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Immuno Genomic® Profile</td>
<td>Genova Dxcs</td>
<td>Aug 2015</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Know Error™</td>
<td>Strand Dxcs</td>
<td>July 2016</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ResponseDX®: Colon</td>
<td>Response Gxcs</td>
<td>Jan 2015</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SEPT9 methylated DNA</td>
<td>Several</td>
<td>Oct 2014</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TransPredict Fc gamma 3A</td>
<td>Transgenomic</td>
<td>Oct 2014</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Castle: Castle Biosciences; Dxcs: Diagnostics; Gxcs: Genetics.

a In a joint venture with Innovative Diagnostic Laboratory.
b For example, ColoVantage®, Epi proColon®.
c ARUP, Quest, Clinical Genomics, Epigenomics.
Summary of Evidence

Diagnostic Tests

For individuals with symptoms of various conditions thought to be hereditary or with a known genetic component who receive testing with a miscellaneous genetic or molecular diagnostic test (eg, DNA Methylation Pathway Profile, Celiac PLUS, GI Effects [Stool], IBD sgi Diagnostic, Know Error, and others), the evidence consists of case series, cross-sectional studies, diagnostic accuracy studies, and cohort studies. Relevant outcomes are overall survival (OS), disease-specific survival, test accuracy and validity, change in disease status, and morbid events. The lack of demonstrated clinical utility of these tests is based on one or both of the following factors: (1) there is no or extremely limited published data addressing the test; and/or (2) there is insufficient evidence demonstrating clinical validity of the test. For each test addressed, a literature review was conducted. The literature review was not comprehensive, but sufficient to establish lack of clinical utility. A test will be removed from this medical policy and addressed separately if it is determined that enough evidence has accumulated for us to reevaluate its potential clinical utility. The evidence is insufficient at this time to determine the effects of the technologies on health outcomes.

For individuals who are being screened for colorectal cancer who receive SEPT9 methylated DNA testing (eg, ColoVantage, Epi proColon, ColonSentry), the evidence includes case-control, cross-sectional, and prospective diagnostic accuracy studies. Relevant outcomes are OS, disease-specific survival, test accuracy and validity, change in disease status, and morbid events. The PRESEPT prospective study estimated the sensitivity and specificity of Epi proColon detection of invasive adenocarcinoma at 48% and 92%, respectively. Other studies were generally low to fair quality. It is unclear whether the test is meant to be used in addition to or in place of existing tests. Based on results from these studies, the clinical validity of SEPT9 methylated DNA screening is limited by low sensitivity of the test given that the sensitivity of the test is lower than imaging screening strategies. Compared with stool-based strategies, the sensitivity is in the same range and the specificity is lower. Optimal intervals for retesting are not known. The evidence is insufficient to determine the effects of the technologies on health outcomes.

Prognostic Tests

For individuals who are diagnosed with various conditions (eg, Crohn disease, thymomas and thymic carcinomas, celiac disease) who receive prognostic testing with a miscellaneous genetic or molecular test (eg, Crohn’s Prognostic, DecisionDx-Thymoma), there are no published studies. Relevant outcomes are OS, disease-specific survival, test accuracy and validity, change in disease
status, and morbid events. The evidence is insufficient to determine the effects of the
technologies on health outcomes.

For individuals who are diagnosed with stage I or II melanoma who receive prognostic testing
with DecisionDx-Melanoma, the evidence includes diagnostic accuracy studies and decision
impact studies. Relevant outcomes are OS, test accuracy and validity, disease-specific survival,
change in disease status, and morbid events. The 3 clinical validity studies enrolled similar or
overlapping patient sets and patients outside of the intended use population (American Joint
Committee on Cancer stage I or II). They reported follow-up that was inadequate to determine
disease-free survival in some patients, and offered inadequate details about treatments received.
One retrospective study has reported that test results are associated with utilization measures
but, without sufficient evidence of clinical validity, it is not known whether the changes in
management were appropriate. The evidence is insufficient to determine the effects of the
technologies on health outcomes.

**Therapeutic Tests**

For individuals who are diagnosed with various conditions (eg, Crohn disease, thymomas and
thymic carcinomas, celiac disease) who receive therapeutic testing with a miscellaneous genetic
or molecular test (eg, ResponseDX: Colon, TransPredict Fc gamma 3A), the evidence includes
case series, cross-sectional studies, diagnostic accuracy studies, and cohort studies. Relevant
outcomes are OS, disease-specific survival, test accuracy and validity, change in disease status,
and morbid events. The lack of demonstrated clinical utility of these tests is based on the
following two factors: (1) there is no or extremely limited published data addressing the test;
and/or (2) there is insufficient evidence demonstrating the clinical validity of the test. For each
test addressed, a literature review was conducted. The literature review was not comprehensive,
but sufficient to establish lack of clinical utility. A test will be removed from this evidence review
and addressed separately if it is determined that enough evidence has accumulated for us to
reevaluate its potential clinical utility. The evidence is insufficient at this time to determine the
effects of the technologies on health outcomes.

**Tests for Future Risk of Disease**

For individuals with a family history of various conditions thought to be hereditary or with a
known genetic component who receive testing for future risk of disease with a miscellaneous
genetic or molecular test (eg, ImmunoGenomic Profile), the evidence includes diagnostic
accuracy studies. Relevant outcomes are OS, disease-specific survival, test accuracy and validity, change in disease status, and morbid events. The lack of demonstrated clinical utility of these tests is based on the following factors: (1) there is no or extremely limited published data addressing the test; and/or (2) there is insufficient evidence demonstrating the clinical validity of the test. For each test addressed, a literature review is conducted. The literature review was not comprehensive, but sufficient to establish lack of clinical utility. A test will be removed from this evidence review and addressed separately if it is determined that enough evidence has accumulated for us to reevaluate its potential clinical utility. The evidence is insufficient at this time to determine the effects of the technologies 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>
</tr>
</thead>
<tbody>
<tr>
<td>Ongoing</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT02355587</td>
<td>An Open, 5-year Registry Study to Track Clinical Application of DecisionDx-Melanoma Gene Expression Profile Assay Results and Associated Patient Outcomes</td>
<td>5000</td>
<td>Feb 2024</td>
</tr>
<tr>
<td>NCT02355574a</td>
<td>An Ongoing, 5-year Post Market Study to Track Clinical Application of DecisionDx-Melanoma Gene Expression Profile (GEP) Assay Results and the Impact on Patient Outcomes and Health Economics</td>
<td>1672</td>
<td>Jun 2024</td>
</tr>
</tbody>
</table>

NCT: national clinical trial.

a Denotes industry-sponsored or cosponsored trial.

Practice Guidelines and Position Statements

Diagnostic Tests

Multiple Conditions

No guidelines or statements were identified.
**Celiac Disease**

In 2013, American College of Gastroenterology (ACG) published an evidence-based consensus algorithm for the diagnosis and management of celiac disease.\(^{37}\) A recommendation for genetic testing using a mutligene panel test (eg, Celiac PLUS) was not included.

**Irritable Bowel Syndrome**

**American College of Gastroenterology (ACG)**

ACG practice guidelines for ulcerative colitis (2010)\(^{47}\) and for Crohn disease (2009)\(^{49}\) did not contain recommendations for multimarker panels that include genetic tests to facilitate diagnosis or prognosis.

**Colorectal Cancer**

**National Comprehensive Cancer Network**

Current National Comprehensive Cancer Network (NCCN) guidelines on colorectal cancer (CRC) screening (v.1.2017) state that tests for methylated SEPT9 DNA "may provide an option for screening for those who refuse other screening modalities but its ability to detect colorectal cancer and advanced adenoma is inferior to other recommended screening modalities. The interval for repeating testing is unknown."\(^{84}\)

**American College of Physicians**

Based on its review of U.S. guidelines, the American College of Physicians (ACP) issued a guidance statement in 2012 on screening for CRC.\(^{85}\) For average-risk adults ages 50 to 75 years, ACP recommended using a stool-based test, flexible sigmoidoscopy, or optical colonoscopy for screening. For high-risk patients, ACP recommended using optical colonoscopy. No recommendation for genetic or molecular testing of average-risk individuals was included.
**U.S. Multi-Society Task Force of Colorectal Cancer**

The U.S. Multi-Society Task Force of Colorectal Cancer represents the American College of Gastroenterology, the American Gastroenterological Association, and the American Society for Gastrointestinal Endoscopy. The 2017 clinical guidelines state that the advantage of SEPT9 assays for CRC screening is convenience. The disadvantage is “markedly inferior performance characteristics compared with FIT [fecal immunochemical test].” The guidelines state that the best frequency for performing the test is unknown and that the task force recommended not using SEPT9 assays for CRC screening.

**Prognostic Tests**

**Crohn Disease**

No guidelines or statements were identified.

**Thymomas and Thymic Carcinomas**

NCCN guidelines for thymomas and thymic carcinomas (v.1.2015) do not address the use of gene expression profiling of tumors of the thymus.

**Cutaneous Melanoma**

NCCN guidelines for melanoma (v.3.2015) state that “while there is interest in newer prognostic molecular techniques such as gene expression profiling to differentiate melanomas at low-versus high-risk for metastasis, routine genetic testing of primary melanoma (before or following sentinel lymph node biopsy) is not recommended outside of a clinical trial.”

**Therapeutic Tests**

**Colon Cancer**

Current NCCN guidelines for colon cancer (v.2.2017) state that it has “not been established if molecular markers are useful in treatment determination (predictive markers) and prognosis.”
Non-Hodgkin Lymphoma

National Comprehensive Cancer Network

Current NCCN guidelines for non-Hodgkin B-cell lymphomas (v.3.2017) do not include a recommendation for genetic testing (eg, TransPredict Fc gamma 3A) to predict response to rituximab therapy.90

American College of Rheumatology

Current (2012) American College of Rheumatology recommendations for the use of disease-modifying antirheumatic drugs and biologic agents in the treatment of rheumatoid arthritis do not address FCGR3 testing.91

U.S. Preventive Services Task Force

Unless otherwise indicated for the diagnostic, prognostic, and therapeutic tests of future risk, no U.S. Preventive Services Task Force (USPSTF) recommendations for genetic or molecular tests have been identified.

The U.S. Preventive Services Task Force updated its recommendations for CRC screening in adults in 2016.51,64 It recommended screening for CRC starting at age 50 years and continuing until age 75 years. The 2016 recommendations differ from the 2008 recommendations in that they do not emphasize specific screening approaches. Rather, they highlight evidence that CRC screening substantially reduces deaths from the disease among adults ages 50 to 75 years, and not enough adults in the United States are using effective preventive interventions. The evidence review supporting the recommendations included a search for studies of blood tests for methylated SEPT9 DNA but concluded that the test “currently has limited evidence evaluating its use.”

National Medicare Coverage

Unless otherwise indicated for the diagnostic, prognostic, and therapeutic tests of future risk, 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 Amendments (CLIA). Genetic tests reviewed in this policy are available under the auspices of 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 these tests.

**References**


43. Shirts B, von Roon AC, Tebo AE. The entire predictive value of the prometheus IBD sgi diagnostic product may be due to the three least expensive and most available components. Am J Gastroenterol. Nov 2012;107(11):1760-1761. PMID 23160303


Date | Comments
--- | ---
11/10/14 | New Policy. Policy created with literature review through September 21, 2014. All tests listed in this policy are considered investigational, and are grouped according to the categories of genetic testing as outlined in medical policy No. 12.04.91.
03/10/15 | Annual Review. Policy updated with literature review through December 9, 2014; references 7-27, 45, 47, 65, and 67 added. Genetic tests added as shown in Table 1. No change to policy statement.
10/13/15 | Annual Review. Policy updated with literature review through July 15, 2015; references 49-58 and 62-64, 81 added. Genetic tests added to Table 1 are ColonSentry and ImmunoGenomic Profile. Appendix Table 1 added with Categories of Genetic Tests included in the policy. Policy statement unchanged. Coding update: CPT codes 81382, 82397, 82784, 86140 and 86255 removed; these are not reviewed in the scope of this policy.
04/01/16 | Update Related Policies. Remove 12.04.38 as it was deleted and replaced with 12.04.517.
05/19/16 | Coding update. Added 84999.
10/01/16 | Annual Review, approved September 13, 2016. Policy updated with literature review through July 5, 2016; references added. Blood DNA tests for colon cancer (ColonSentry, SEPT9 methylated DNA- ColoVantage, Epi proColon) moved to policy 2.04.141, that is now included in the Related Policies section. Policy statements unchanged.
11/01/16 | Coding update, approved October 11, 2016. Codes listed within verbiage and test names in Coding section removed; these were informational only. Update Related Policies. Removed 2.04.141 as it was replaced with 12.04.141. Added 12.04.141 to Related Policies section.
07/07/17 | Policy moved into new format, no changes to policy statement.
09/01/17 | Annual review, approved August 22, 2017. Policy updated with literature review through July 5, 2016; references 51, 57-58, 64, 67, and 86 added. Several guidelines updated with current versions. Policy statements updated to organize types of tests with language that corresponds to related policy; all tests remain investigational. Removed CPT codes 83520 and 86021.

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  Email AppealsDepartmentInquiries@Premera.com

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U.S. Department of Health and Human Services
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