Reimbursement Policy

Genetic Testing Panels

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Related Policies

R17 Laboratory Services
R21 Precertification

Related Coverage Policies
CP0514 Genetic Testing for Reproductive Carrier Screening and Prenatal Diagnosis
CP0052 Genetic Testing for Hereditary and Multifactorial Conditions

INSTRUCTIONS FOR USE
Reimbursement policies are intended to supplement certain standard benefit plans. Please note, the terms of an individual’s particular benefit plan document [Group Service Agreement (GSA), Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which a reimbursement policy is based. For example, an individual’s benefit plan document may contain specific language which contradicts the guidance outlined in a reimbursement policy. In the event of a conflict, an individual’s benefit plan document always supersedes the information in a reimbursement policy. Reimbursement terms in agreements with participating health care providers may also supersedes the information in a reimbursement policy. Proprietary information of Cigna. Copyright ©2020 Cigna

Overview

Molecular genetic testing applies to human somatic and germline testing and nucleic acid testing in pathogens or organisms.

There is wide variation of the individual components within a molecular genetic testing panel from laboratory to laboratory. This policy summarizes the reimbursement for genetic tests billed individually or in combination with a more comprehensive genetic testing panel code.

This policy applies to both CMS 1500 and UB04 claim forms and their electronic counterparts.

Reimbursement Policy

Cigna does not provide separate reimbursement for individual gene codes when the gene tests performed can be collectively represented by a single molecular genetic test panel code. When the individual gene codes that comprise a molecular genetic testing panel are performed, the panel code should be reported. If reported separately, the individual gene codes will be re-bundled into a single panel code that is similar to or more accurately reflects the service provided for reimbursement and medical necessity consideration.

Cigna reviews the genes tested and related components in order to determine whether they are aligned with a particular recognized panel.

If both a panel code and the individual gene codes that constitute the panel are billed, only the panel code will be reimbursed.
Please note that several genetic testing codes are subject to precertification requirements. This policy does not supersede precertification requirements or existing code editing.

**General Background**

A lab panel is a collection of individual tests performed on the same date for a specific purpose. The panel test typically is represented by a single CPT® or HCPCS® code. The individual tests within a panel typically have their own specific assigned CPT® or HCPCS® code.

Lab panels offer various advantages to the laboratories performing the tests (labor efficiency, potential for automation and reduced costs through performing large numbers of the same kinds of tests each day) as well as to end users such as ordering physicians and hospitals (more comprehensive testing, rapid turn-around and lower prices).

**The following panel codes are subject to unbundling edits:**

**Ashkenazi Jewish Associated Disorder Panel (CPT® Code 81412)** is defined by the AMA as “Ashkenazi Jewish associated disorders (e.g., Bloom syndrome, Canavan disease, cystic fibrosis, familial dysautonomia, Fanconi anemia group C, Gaucher disease, Tay-Sachs disease), genomic sequence analysis panel, must include sequencing of at least 9 genes, including ASPA, BLM, CFTR, FANCC, GBA, HEXA, IKBKAP, MCOLN1, and SMPD1.”

In the event that multiple panel specific units are identified on a claim(s) from the same provider on the same date of service, the individual genetic testing codes will be re-bundled and reimbursement will be made based on the panel code of CPT® Code 81412 which is similar to and more accurately reflects the service provided.

**Severe Inherited Condition Panel (CPT® Code 81443)** is defined by the AMA as: “Genetic testing for severe inherited conditions (e.g., cystic fibrosis, Ashkenazi Jewish-associated disorders [e.g., Bloom syndrome, Canavan disease, Fanconi anemia type C, mucolipidosis type VI, Gaucher disease, Tay-Sachs disease], beta hemoglobinopathies, phenylketonuria, galactosemia), genomic sequence analysis panel, must include sequencing of at least 15 genes (eg, ACADM, ARSA, ASPA, ATP7B, BCKDHA, BCKDHB, BLM, CFTR, DHCR7, FANCC, G6PC, GAA, GALT, GBA, GBE1, HBB, HEXA, IKBKAP, MCOLN1, PAH).”

In the event that multiple panel specific units are identified on a claim(s) from the same provider on the same date of service, the individual genetic testing codes will be re-bundled and reimbursement will be made based on the panel code of CPT® Code 81443 which is similar to and more accurately reflects the service provided.

**Tumor Profiling Panel (CPT® Code 81445, 81450, 81455)** is defined by the AMA as:

**81445**: 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, PDGFR, PDGFRB, PGR, PIK3CA, PTEN, RET), interrogation for sequence variants and copy number variants or rearrangements, if performed.

**81450**: 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.

**81455**: 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, PDGFR, PDGFRB, PGR, PIK3CA, PTEN, RET), interrogation for sequence variants and copy number variants or rearrangements, if performed.
In the event that multiple panel specific units are identified on a claim(s) from the same provider on the same date of service, the individual genetic testing codes will be re-bundled and reimbursement will be made based on the panel code(s) 81445 or 81450 or 81455 which are similar to and more accurately reflects the service provided.

**Hereditary Cancer Panel (CPT® Code 81432, 81433, 81435, 81436)** is defined by the AMA as:

81432: Hereditary breast cancer-related disorders (eg, hereditary breast cancer, hereditary ovarian cancer, hereditary endometrial cancer); genomic sequence analysis panel, must include sequencing of at least 10 genes, always including BRCA1, BRCA2, CDH1, MLH1, MSH2, MSH6, PALB2, PTEN, STK11, and TP53

81433: Hereditary breast cancer-related disorders (eg, hereditary breast cancer, hereditary ovarian cancer, hereditary endometrial cancer); duplication/deletion analysis panel, must include analyses for BRCA1, BRCA2, MLH1, MSH2, and STK11

81435: Hereditary colon cancer disorders (eg, Lynch syndrome, PTEN hamartoma syndrome, Cowden syndrome, familial adenomatosis polyposis); genomic sequence analysis panel, must include sequencing of at least 10 genes, including APC, BMPR1A, CDH1, MLH1, MSH2, MSH6, MUTYH, PTEN, SMAD4, and STK11

81436: Hereditary colon cancer disorders (eg, Lynch syndrome, PTEN hamartoma syndrome, Cowden syndrome, familial adenomatosis polyposis); duplication/deletion analysis panel, must include analysis of at least 5 genes, including MLH1, MSH2, EPCAM, SMAD4, and STK11

In the event that multiple panel specific units are identified on a claim(s) from the same provider on the same date of service, the individual genetic testing codes will be re-bundled and reimbursement will be made based on the panel code(s) 81432 or 81433 or 81435 or 81436 which are similar to and more accurately reflects the service provided.

**Nucleic Acid Sexually Transmitted Disease Panel (CPT® Code 87800, 87801)** is defined by the AMA as:

87800: Infectious agent detection by nucleic acid (DNA or RNA), multiple organisms; direct probe(s) technique

87801: Infectious agent detection by nucleic acid (DNA or RNA), multiple organisms; amplified probe(s) technique

In the event that multiple panel specific units are identified on a claim(s) from the same provider on the same date of service, the individual genetic testing codes will be re-bundled and reimbursement will be made based on the panel code(s) 87800 or 87801 which are similar to and more accurately reflects the service provided.

**Coding/Billing Information**

**Note:** 1) This list of codes may not be all-inclusive.

2) Deleted codes and codes which are not effective at the time the service is rendered are not eligible for reimbursement.

**Ashkenazi Jewish Associated Disorder Panel**

<table>
<thead>
<tr>
<th>CPT®® Codes</th>
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<tbody>
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<td>81412</td>
<td>Ashkenazi Jewish associated disorders (eg, Bloom syndrome, Canavan disease, cystic fibrosis, familial dysautonomia, Fanconi anemia group C, Gaucher disease, Tay-Sachs disease), genomic sequence analysis panel, must include sequencing of at least 9 genes, including ASPA, BLM, CFTR, FANCC, GBA, HEXA, IKBKAP, MCOLN1, and SMPD1</td>
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**Severe Inherited Condition Panel**
### Tumor Profiling Panel

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<tr>
<td><strong>81445</strong></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, PIK3CA, PTEN, RET), interrogation for sequence variants and copy number variants or rearrangements, if performed.</td>
</tr>
<tr>
<td><strong>81450</strong></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>
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<tr>
<td><strong>81455</strong></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, PDGFRα, PDGFRβ, PGR, PIK3CA, PTEN, RET), interrogation for sequence variants and copy number variants or rearrangements, if performed.</td>
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### Hereditary Cancer Panel

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<td>Hereditary breast cancer-related disorders (eg, hereditary breast cancer, hereditary ovarian cancer, hereditary endometrial cancer); genomic sequence analysis panel, must include sequencing of at least 10 genes, always including BRCA1, BRCA2, CDH1, MLH1, MSH2, MSH6, PALB2, PTEN, STK11, and TP53</td>
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<td>Hereditary breast cancer-related disorders (eg, hereditary breast cancer, hereditary ovarian cancer, hereditary endometrial cancer); duplication/deletion analysis panel, must include analyses for BRCA1, BRCA2, MLH1, MSH2, and STK11</td>
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<td>Hereditary colon cancer disorders (eg, Lynch syndrome, PTEN hamartoma syndrome, Cowden syndrome, familial adenomatosis polyposis); genomic sequence analysis panel, must include sequencing of at least 10 genes, including APC, BMPR1A, CDH1, MLH1, MSH2, MSH6, MUTYH, PTEN, SMAD4, and STK11</td>
</tr>
<tr>
<td><strong>81436</strong></td>
<td>Hereditary colon cancer disorders (eg, Lynch syndrome, PTEN hamartoma syndrome, Cowden syndrome, familial adenomatosis polyposis); duplication/deletion analysis panel, must include analysis of at least 5 genes, including MLH1, MSH2, EPCAM, SMAD4, and STK11</td>
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### Nucleic Acid Sexually Transmitted Disease Panel

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<td><strong>87800</strong></td>
<td>Infectious agent detection by nucleic acid (DNA or RNA), multiple organisms; direct probe(s) technique</td>
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<tr>
<td><strong>87801</strong></td>
<td>Infectious agent detection by nucleic acid (DNA or RNA), multiple organisms; amplified probe(s) technique</td>
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References


Policy History/Update

<table>
<thead>
<tr>
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<tr>
<td>05/18/2020</td>
<td>Effective date for Nucleic Acid Sexually Transmitted Disease Panel bundling.</td>
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<td>04/06/2020</td>
<td>Effective date for Tumor Profiling Panel and Hereditary Cancer Panel bundling.</td>
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<tr>
<td>02/26/2020</td>
<td>Notification of Nucleic Acid Sexually Transmitted Disease Panel bundling effective 05/18/2020</td>
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<td>01/16/2020</td>
<td>Notification of Tumor Profiling Panel and Hereditary Cancer Panel bundling effective 04/06/2020</td>
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<td>03/15/2019</td>
<td>Policy effective date</td>
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<td>12/15/2018</td>
<td>Notification of policy effective date of 03/15/2019</td>
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