

# LCD - Biomarkers Overview (L35062)

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## Contractor Information

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATES
<a href="#">Novitas Solutions, Inc.</a>	A and B MAC	04111 - MAC A	J - H	Colorado
<a href="#">Novitas Solutions, Inc.</a>	A and B MAC	04112 - MAC B	J - H	Colorado
<a href="#">Novitas Solutions, Inc.</a>	A and B MAC	04211 - MAC A	J - H	New Mexico
<a href="#">Novitas Solutions, Inc.</a>	A and B MAC	04212 - MAC B	J - H	New Mexico
<a href="#">Novitas Solutions, Inc.</a>	A and B MAC	04311 - MAC A	J - H	Oklahoma
<a href="#">Novitas Solutions, Inc.</a>	A and B MAC	04312 - MAC B	J - H	Oklahoma
<a href="#">Novitas Solutions, Inc.</a>	A and B MAC	04411 - MAC A	J - H	Texas
<a href="#">Novitas Solutions, Inc.</a>	A and B MAC	04412 - MAC B	J - H	Texas
<a href="#">Novitas Solutions, Inc.</a>	A and B MAC	04911 - MAC A	J - H	Colorado New Mexico Oklahoma Texas
<a href="#">Novitas Solutions, Inc.</a>	A and B MAC	07101 - MAC A	J - H	Arkansas
<a href="#">Novitas Solutions, Inc.</a>	A and B MAC	07102 - MAC B	J - H	Arkansas
<a href="#">Novitas Solutions, Inc.</a>	A and B MAC	07201 - MAC A	J - H	Louisiana
<a href="#">Novitas Solutions, Inc.</a>	A and B MAC	07202 - MAC B	J - H	Louisiana
<a href="#">Novitas Solutions, Inc.</a>	A and B MAC	07301 - MAC A	J - H	Mississippi
<a href="#">Novitas Solutions, Inc.</a>	A and B MAC	07302 - MAC B	J - H	Mississippi
<a href="#">Novitas Solutions, Inc.</a>	A and B MAC	12101 - MAC A	J - L	Delaware
<a href="#">Novitas Solutions, Inc.</a>	A and B MAC	12102 - MAC B	J - L	Delaware
<a href="#">Novitas Solutions, Inc.</a>	A and B MAC	12201 - MAC A	J - L	District of Columbia
<a href="#">Novitas Solutions, Inc.</a>	A and B MAC	12202 - MAC B	J - L	District of Columbia
<a href="#">Novitas Solutions, Inc.</a>	A and B MAC	12301 - MAC A	J - L	Maryland
<a href="#">Novitas Solutions, Inc.</a>	A and B MAC	12302 - MAC B	J - L	Maryland
<a href="#">Novitas Solutions, Inc.</a>	A and B MAC	12401 - MAC A	J - L	New Jersey
<a href="#">Novitas Solutions, Inc.</a>	A and B MAC	12402 - MAC B	J - L	New Jersey
<a href="#">Novitas Solutions, Inc.</a>	A and B MAC	12501 - MAC A	J - L	Pennsylvania
<a href="#">Novitas Solutions, Inc.</a>	A and B MAC	12502 - MAC B	J - L	Pennsylvania
<a href="#">Novitas Solutions, Inc.</a>	A and B MAC	12901 - MAC A	J - L	Delaware

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATES
				District of Columbia Maryland New Jersey Pennsylvania

# LCD Information

## Document Information

### LCD ID

L35062

### LCD Title

Biomarkers Overview

### Proposed LCD in Comment Period

N/A

### Source Proposed LCD

[DL35062](#)

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### Revision Effective Date

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### Revision Ending Date

N/A

### Retirement Date

N/A

### Notice Period Start Date

10/13/2016

### Notice Period End Date

11/30/2016

## Issue

### Issue Description

The new Pharmacogenomics Testing LCD, L39073, addresses services that were included in Biomarkers Overview. Therefore, the LCD is being revised to remove any overlapping information. Please refer to the Pharmacogenomics

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Testing LCD for coverage information.

## **CMS National Coverage Policy**

This LCD supplements but does not replace, modify or supersede existing Medicare applicable National Coverage Determinations (NCDs) or payment policy rules and regulations for biomarker overview services. Federal statute and subsequent Medicare regulations regarding provision and payment for medical services are lengthy. They are not repeated in this LCD. Neither Medicare payment policy rules nor this LCD replace, modify or supersede applicable state statutes regarding medical practice or other health practice professions acts, definitions and/or scopes of practice. All providers who report services for Medicare payment must fully understand and follow all existing laws, regulations and rules for Medicare payment for biomarker overview services and must properly submit only valid claims for them. Please review and understand them and apply the medical necessity provisions in the policy within the context of the manual rules. Relevant CMS manual instructions and policies regarding services may be found in the following Internet-Only Manuals (IOMs) published on the CMS Web site.

### **IOM Citations:**

- CMS IOM Publication 100-02, *Medicare Benefit Policy Manual*, Chapter 15, Sections 80.1, 80.1.1, 80.1.2, 80.1.3, Laboratory services must meet applicable requirements of CLIA, and Section 280, Preventive and Screening Services
- CMS IOM Publication 100-08, *Medicare Program Integrity Manual*,
  - Chapter 3, Sections 3.4.1.3 Diagnosis Code Requirements and 3.6.2.3 Limitation of Liability Determinations
  - Chapter 13, Section 13.5.4 Reasonable and Necessary Provision in an LCD

### **Social Security Act (Title XVIII) Standard References:**

- Title XVIII of the Social Security Act, Section 1862(a)(1)(A) states that no Medicare payment may be made for items or services which are not reasonable and necessary for the diagnosis or treatment of illness or injury.
- Title XVIII of the Social Security Act, Section 1862(a)(7). This section excludes routine physical examinations.

### **Code of Federal Regulations (CFR) References:**

- CFR, Title 42 Section 410.32: Diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests: Conditions
- CFR, Title 42 Section 411.15: Particular services excluded from coverage

## **Coverage Guidance**

### **Coverage Indications, Limitations, and/or Medical Necessity**

Compliance with the provisions in this LCD may be monitored and addressed through post payment data analysis and subsequent medical review audits.

### **History/Background and/or General Information**

The emergence of personalized laboratory medicine has been characterized by a multitude of testing options which may more precisely pinpoint management needs of individual patients. As a result, the growing compendium of biomarkers requires a more careful evaluation by both clinicians and laboratorians as to what testing configurations

can more optimally realize the promises of personalized medicine. There are a plethora of burgeoning tools, including both gene-based (genomic) and protein-based (proteomic) assay formats, in tandem with more conventional (longstanding) flow cytometric, cytogenetic, etc. biomarkers. Classified somewhat differently, there are highly diverse approaches ranging from single mutation biomarkers to multiple biomarker platforms, the latter of which often depend upon sophisticated biomathematical interpretative algorithms. This policy will provide guidance on the broad range of (recently coded) biomarkers, and how such a wide array of testing platforms can be best accommodated by this local Medicare Administrative Contractor.

Medicare coverage for screening of those individuals with a family history of certain disease is covered only for a limited number of services as listed in the Section 280 – Preventative and Screening Services of the IOM 100-02, *Medicare Benefit Policy Manual*, Chapter 15.

Tests performed without relationship to treatment or diagnosis of a patient with no findings or history for a specific illness, symptom, complaint or injury unless set exclusion are so noted in Title 42 CFR, Section 411.15(a)(1).

Local Medicare coverage of such biomarkers must be predicated upon three fundamental principles:

First, there must be an underlying performance of acceptable, high-quality analytical validity for all such laboratory testing. As a result, the laboratory shall have available upon request:

- Analytical and clinical validation reports for Clinical Laboratory Improvement Amendments (CLIA), including the test description, intended use, and indications for testing.
- If applicable, all formal, written minutes and correspondences (including any Q & A and supporting documentation) with the New York State Department of Health (NYSDOH) or the United States (U.S.) Food and Drug Administration (FDA).
- Most recent inspection results (including recommendations) or scheduled inspection(s) from CLIA, College of American Pathologists (CAP), or NYSDOH, as applicable.

Second, there must be an appreciation of evidence-in-transition where new biomarkers should be brought on-line in harmonization with their proven clinical validity/utility (CVU). Although analytical validity is an equally important metric, it remains more outside of a payer's purview to conduct such detailed evaluations. Therefore, in the absence of a standard CVU referee process (e.g., although FDA labeling of biomarkers can be a helpful adjunct, it may not always be relevant), the key imperative is for medical necessity to be reflected by the clear articulation of a particular biomarker niche.

Third, there must be a recognized decision impact of such biomarkers by the clinical community. In other words, there must be acceptance/uptake of specific testing into patient management. It should be taken into account that to reach the medical necessity threshold, such acceptance should be based on the strongest evidence available, ideally from along the spectrum of high-quality masked, randomized controlled clinical trials, and much less preferably from lower levels of evidence, which are predicated upon expert opinion only without primary study data.

Per above, it is relevant to categorize biomarkers into functional clusters which, in turn, can enable longitudinal coverage guidance that is most relevant to the Medicare program mission:

**The commercial availability does not ensure that a molecular diagnostic test is indicated for clinical application. Molecular diagnostic testing is a rapidly evolving science in which the significance of detecting specific mutations has yet to be clarified in many circumstances. Analytical and clinical validity as well as clinical utility are the responsibility of the provider, and all testing must meet standards of care.**

## **Covered Indications**

## 1. GERMLINE (HEREDITARY) MUTATIONS

Medicare considers genetic testing medically necessary to establish a molecular diagnosis of an inheritable disease when all of the following criteria are met:

- The beneficiary must display clinical features of an associated disease, but noting that coverage of molecular testing for carrier status or family studies is considered screening and is statutorily excluded from coverage; and
- The result of the test will directly impact the treatment being delivered to the beneficiary; and
- A definitive diagnosis remains uncertain after history, physical examination, pedigree analysis, genetic counseling, and completion of conventional diagnostic studies.

**Note:** The following two germline hereditary mutation tests will be considered medically reasonable and necessary when performed for evaluation of venous thromboembolism. Refer to ICD-10 Code Group 3 in the related Local Coverage Article: Billing and Coding: Biomarkers Overview A56541.

- Factor II (F2 gene)
- Factor V (F5 gene)

\* While not required for payment, NCCN Guidelines recommend referral to a cancer genetics professional with expertise and experience in cancer genetics prior to genetic testing and after genetic testing. Examples of cancer genetics professionals with expertise and experience in cancer genetics include: an American Board of Medical Genetics or American Board of Genetic Counseling certified or board eligible Clinical Geneticist, Medical Geneticist or Genetic Counselor not employed by a commercial genetic testing laboratory (excludes individuals employed by or contracted with a laboratory that is part of an Integrated Health System which routinely delivers health care services beyond just the laboratory test itself as these individuals are also considered independent); medical oncologist, obstetrician-gynecologist or other physician trained in medical cancer genetics, a genetic nurse credentialed as either a Genetic Clinical Nurse or an Advanced Practice Nurse in Genetics by either the Genetic Nursing Credentialing Commission (GNCC) or the American Nurses Credentialing Center (ANCC) who is not employed by a commercial genetic testing laboratory (excludes individuals employed by or contracted with a laboratory that is part of an Integrated Health System which routinely delivers health care services beyond just the laboratory test itself as these individuals are also considered independent).

## 2. SOMATIC MUTATIONS, ONCOLOGY:

- Please Refer to LCD L35396, Biomarkers for Oncology.

This LCD imposes frequency limitations. For frequency limitations please refer to the Utilization Guidelines section below.

**Notice:** Services performed for any given diagnosis must meet all of the indications and limitations stated in this policy, the general requirements for medical necessity as stated in CMS payment policy manuals, any and all existing CMS national coverage determinations, and all Medicare payment rules.

### Summary of Evidence

N/A

## Analysis of Evidence (Rationale for Determination)

N/A

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# General Information

## Associated Information

Please refer to the related Local Coverage Article: Billing and Coding: Biomarkers Overview, A56541 for all coding information.

## Documentation Requirements

1. All documentation must be maintained in the patient's medical record and made available to the contractor upon request.
2. Every page of the record must be legible and include appropriate patient identification information (e.g., complete name, dates of service[s]). The documentation must include the legible signature of the physician or non-physician practitioner responsible for and providing the care to the patient.
3. The medical record documentation must support the medical necessity of the services as stated in this policy.

## Utilization Guidelines

In accordance with CMS Ruling 95-1 (V), utilization of these services should be consistent with locally acceptable standards of practice, whereby more than once per lifetime testing is not deemed medically necessary, except under special clinical scenarios which will be handled through the redetermination process. The medical record must support the medical necessity of the increased frequency.

Autoimmune (rheumatoid arthritis), is limited to two services per rolling year per beneficiary.

## Sources of Information

Contractor is not responsible for the continued viability of websites listed.

Other Contractor Policies

First Coast Service Options (FCSO) LCD, L35366, CYP2C19, CYP2D6, CYP2C9, and VKORC1 Genetic Testing

Palmetto GBA

Contractor Medical Directors

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  137. <http://ghr.nlm.nih.gov/condition/canavan-disease>
  138. <http://ghr.nlm.nih.gov/condition/maple-syrup-urine-disease>
  139. <http://ghr.nlm.nih.gov/condition/glycogen-storage-disease-type-i>
  140. <http://ghr.nlm.nih.gov/condition/gaucher-disease>
  141. <http://www.ncbi.nlm.nih.gov/books/NBK1269/>
  142. <http://ghr.nlm.nih.gov/gene/GJB2>
  143. <http://www.ncbi.nlm.nih.gov/books/NBK1536/>
  144. <http://www.ncbi.nlm.nih.gov/books/NBK1272/>
  145. <http://ghr.nlm.nih.gov/condition/tay-sachs-disease>
  146. <http://www.ncbi.nlm.nih.gov/books/NBK1218/>
  147. <http://ghr.nlm.nih.gov/condition/hemochromatosis>
  148. <http://www.ncbi.nlm.nih.gov/books/NBK1440/>
  149. <http://ghr.nlm.nih.gov/gene/HFE>
  150. <http://ghr.nlm.nih.gov/gene/HBA1>

151. <http://www.ncbi.nlm.nih.gov/books/NBK1435/>
152. <http://ghr.nlm.nih.gov/gene/HBA2>
153. <http://ghr.nlm.nih.gov/condition/familial-dysautonomia>
154. <http://www.ncbi.nlm.nih.gov/books/NBK1180/>
155. <http://ghr.nlm.nih.gov/gene/KCNH2>
156. <http://www.ncbi.nlm.nih.gov/books/NBK1129/> + Input from Palmetto GBA.
157. <http://ghr.nlm.nih.gov/condition/mucopolidosis-type-iv>
158. <http://www.ncbi.nlm.nih.gov/books/NBK1214/>
159. <http://ghr.nlm.nih.gov/gene/MTHFR>
160. <http://www.lyncscreening.net/developmen/supporting-guidelines/nccn-practice-guidelines/>
161. <http://ghr.nlm.nih.gov/condition/cowden-syndrome>
162. <http://www.ncbi.nlm.nih.gov/books/NBK1488/>
163. <http://www.cancer.gov/cancertopics/factsheet/Risk/BRCA>

There were extensive in-person consultations with both CAC representatives and nationally-recognized experts in order to assist with the above medical necessity language and procedure-to-diagnosis code pairings.

## Revision History Information

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASONS FOR CHANGE
12/12/2021	R22	LCD revised and published on 12/09/21 effective for dates of service on and after 12/12/21 in response to the new Pharmacogenomic LCD becoming effective. The following information has been removed as the content is addressed in the new LCD. In the 'Covered Indications' section, Bullet 2 Pharmacogenomics was removed and Bullet 3 Somatic Mutations, Oncology was renumbered to Section 2 and language was removed for CYP2CP Genotyping from this section. Minor formatting changes were made throughout.	<ul style="list-style-type: none"> <li>Other (to remove overlapping information due to the new Pharmacogenomics LCD becoming effective)</li> </ul>
07/01/2020	R21	LCD revised and published on 06/25/2020 effective for dates of service on and after 07/01/2020 as a non-discretionary update to remove the table for Germline Mutation for coverage or noncoverage and the paragraph preceding the table that addressed coverage status of various germline mutations listed in the table, to remove the statement that Biomarkers not addressed in this LCD or any other Novitas LCD will be considered not reasonable and necessary unless specifically covered by national policy, and to remove a duplicate statement to refer to the utilization guideline section for frequency limitations. These services will now be covered when provided as outlined in the LCD consistent with CMS direction.	<ul style="list-style-type: none"> <li>Other (Revised in response to CMS direction.)</li> </ul>

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASONS FOR CHANGE
11/07/2019	R20	LCD revised and published 11/7/2019 to completely remove the Coding Information Section from this LCD per CMS Change Request 10901. Please see the related Billing and Coding Article, A56541 for all codes and information related to coding and billing.	<ul style="list-style-type: none"> <li>Other (CMS Change Request 10901)</li> </ul>
05/30/2019	R19	LCD revised and published on 05/30/2019. Consistent with Change Request (CR) 10901 all CPT and ICD-10 codes have been removed from the LCD and placed in the related Billing and Coding Article, A56541. Since the CPT codes have been removed from the LCD, the Germline Mutation Table has been included in the related Article with the applicable CPT codes. A link for A56541 has been added as a related document. The references have been moved to the Bibliography section. There has been no change in coverage with this LCD revision.	<ul style="list-style-type: none"> <li>Other (Change in LCD process per CMS CR 10901)</li> </ul>
01/01/2019	R18	LCD revised and published on 02/14/2019 effective for dates of service on and after 01/01/2019 to reflect the annual CPT/HCPCS code updates. The following CPT/HCPCS code(s) have been added to the Germline Table as covered and also added to Group 1 Codes: 81329, 81336 and 81337. For the following CPT/HCPCS code either the short description and/or the long description was changed. Depending on which description is used in this LCD, there may not be any change in how the code displays in the document: 81244. CMS IOM language has been removed from the LCD per Change Request 10901.	<ul style="list-style-type: none"> <li>Revisions Due To CPT/HCPCS Code Changes</li> <li>Other (CMS Requirement)</li> </ul>
10/01/2018	R17	<p>LCD revised and published on 10/25/2018 effective for dates of service on and after 10/01/2018 to reflect the ICD-10-CM Annual Code Updates and annual review. The following ICD-10-CM code(s) have undergone a descriptor change: I63.333, I63.343. Per annual review, updated the references in the "CMS National Coverage Policy" section and made standard policy formatting revisions throughout the policy without a change in coverage content.</p> <p>At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; therefore, not all the fields included on the LCD are applicable as noted in this policy.</p>	<ul style="list-style-type: none"> <li>Revisions Due To ICD-10-CM Code Changes</li> <li>Other (Annual Review)</li> </ul>

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASONS FOR CHANGE
03/08/2018	R16	<p>LCD updated on 03/08/2018 for administrative purposes. No changes have been made to the LCD content.</p> <p>At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; therefore, not all the fields included on the LCD are applicable as noted in this policy.</p>	<ul style="list-style-type: none"> <li>Other (Administrative Update-No content change.)</li> </ul>
01/01/2018	R15	<p>LCD revised and published on 01/25/2018 effective for dates of service on and after 01/01/2018 to reflect the annual CPT/HCPCS code updates. The following CPT code(s) have been added to the Group 1 codes with no diagnosis limitations applied and have also been added to the Germline Mutation Table as covered: 81258, 81259, and 81269. For the following CPT code(s) either the short description and/or the long description has been changed. Depending on which description is used in this LCD, there may not be any change in how the codes display in the document: 81257 (Group 1 CPT code) and 81439 (Group 3 CPT code).</p> <p>At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; therefore, not all the fields included on the LCD are applicable as noted in this policy.</p>	<ul style="list-style-type: none"> <li>Revisions Due To CPT/HCPCS Code Changes</li> </ul>
12/14/2017	R14	<p>LCD revised and published on 12/14/2017 to add the statement from L35396-Biomarkers for Oncology in order to provide clarification regarding biomarkers considered reasonable and necessary.</p> <p>At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; therefore, not all the fields included on the LCD are applicable as noted in this policy.</p>	<ul style="list-style-type: none"> <li>Other (Clarification)</li> </ul>
10/01/2017	R13	<p>LCD revised and published on 10/05/2017 effective for dates of service on and after 10/01/2017 to reflect the ICD-10 Annual Code Updates. The following ICD-10 code(s) have undergone a descriptor change - Group 1 Codes: I63.323, I63.333, I63.513, I63.523, I63.533.</p>	<ul style="list-style-type: none"> <li>Revisions Due To ICD-10-CM Code Changes</li> <li>Other (Inquiry and Clarification)</li> </ul>

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASONS FOR CHANGE
		<p>Effective for dates of service on and after 08/09/2017 the following ICD-10 code has been added to Group 5 codes: Z94.1. Group 1 Paragraph statement has been revised to clarify that only CPT codes listed in ICD-10 code groups 1 through 5 are subject to diagnosis-to-procedure code limitations at this time.</p> <p>At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; therefore, not all the fields included on the LCD are applicable as noted in this policy.</p>	
02/01/2017	R12	LCD revised and published on 05/11/2017 effective for dates of service on and after 02/01/2017 to add CPT/HCPCS code 0001U to Group 1 CPT codes and to the Germline Table as covered; there are no diagnosis code limitations applied at this time.	<ul style="list-style-type: none"> <li>Revisions Due To CPT/HCPCS Code Changes</li> </ul>
01/01/2017	R11	LCD revised and published on 03/16/2017 to add sources submitted for a reconsideration request to add a six-gene panel for Major Depressive Disorder. No change has been made to the content of the policy.	<ul style="list-style-type: none"> <li>Reconsideration Request</li> </ul>
01/01/2017	R10	LCD revised and published on 01/12/2017 effective for dates of service on and after 01/01/2017 to reflect the annual CPT/HCPCS code updates. The following CPT/HCPCS codes 81280, 81281, and 81282 have been deleted and therefore removed from group 3 of the LCD. The following CPT/HCPCS codes 81413, 81414, and 81439 have been added to group 3 of the LCD. The Germline Mutation Table has been modified to reflect the changes.	<ul style="list-style-type: none"> <li>Revisions Due To CPT/HCPCS Code Changes</li> </ul>
12/01/2016	R9	<p>LCD posted for notice on 10/13/2016 with a notice end date of 11/30/2016. LCD becomes effective for dates of service on and after 12/01/2016.</p> <p>05/19/2016 DL35062 Draft LCD Posted for Comment.</p>	<ul style="list-style-type: none"> <li>Automated Edits to Enforce Reasonable &amp; Necessary Requirements</li> </ul>
10/01/2016	R8	LCD revised and published on 09/29/2016 effective for dates of service on and after 10/01/2016 to reflect the ICD-10 Annual Code Updates. The following ICD-10 code(s) have been added to Group 1: I63.013, I63.033, I63.113, I63.133, I63.213, I63.233, I63.313, I63.323, I63.333, I63.343, I63.413, I63.423, I63.433, I63.443, I63.513, I63.523, I63.533, and I63.543. The following	<ul style="list-style-type: none"> <li>Other (Inquiry)</li> <li>Revisions Due To ICD-10-CM Code Changes</li> </ul>



REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASONS FOR CHANGE
		ICD-10 code has been added to Group 2: F32.89. The dual diagnosis requirement in Group 1 for CPT code 81225 has been removed effective for dates of service on and after 10/01/2015.	
01/01/2016	R7	LCD revised and published on 01/28/2016 effective for dates of service on and after 01/01/2016 to reflect the annual CPT/HCPCS code updates. The following CPT/HCPCS code has been added to the Germline Mutation table as covered and to Group 1 Codes: <i>81162</i> . For the following CPT/HCPCS code either the short description and/or the long description was changed. Depending on which description is used in this LCD, there may not be any change in how the code displays in the document: <i>81355</i> . The following CPT/HCPCS code has been deleted: <i>81412</i> .	<ul style="list-style-type: none"> <li>Revisions Due To CPT/HCPCS Code Changes</li> </ul>
10/01/2015	R6	LCD revised and published 09/11/2015 to add many sources submitted with reconsideration request to add Genecept Assay. No changes made to the content of LCD.	<ul style="list-style-type: none"> <li>Reconsideration Request</li> </ul>
10/01/2015	R5	LCD revised and published on 06/25/2015.	<ul style="list-style-type: none"> <li>New/Updated Technology</li> <li>Revisions Due To CPT/HCPCS Code Changes</li> </ul>
10/01/2015	R4	LCD revised and published on 08/14/2014 to clarify that effective 07/01/2014 an indefinite suspension of requests for new local coverage appropriateness protocols was implemented.	<ul style="list-style-type: none"> <li>Provider Education/Guidance</li> </ul>
10/01/2015	R3	LCD revised and published on 07/24/2014, effective for dates of service on or after 10/01/2014 to remove the age restrictions from the following biomarkers: Mlh 1 gene full seq, Mlh 1 gene known variants, Mlh 1 gene dup/delete variant, Microsatellite instability, PTEN gene analysis, full sequence, PTEN gene known familial variants, PTEN gene duplication/deletion.	<ul style="list-style-type: none"> <li>Provider Education/Guidance</li> </ul>
10/01/2015	R2	LCD revised and published on 06/26/2014 to delete a reference to the Coverage with Evidence (CED) process, which is not exactly the same as the local coverage appropriateness protocol approach described in this LCD effective for dates of service on or after 10/01/2014.	<ul style="list-style-type: none"> <li>Other (Clarification)</li> </ul>

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASONS FOR CHANGE
10/01/2015	R1	LCD revised to delete selected age-based limits in an effort to be more compliant/consistent with December 2013 United States Preventive Services Task Force (USPSTF) recommendations on BRCA1 and BRCA2 gene mutation testing in response to a reconsideration request. (LCD updated 05/15/2014)	<ul style="list-style-type: none"> <li>Reconsideration Request</li> </ul>

## Associated Documents

### Attachments

N/A

### Related Local Coverage Documents

#### Articles

[A56541 - Billing and Coding: Biomarkers Overview](#)

[A58917 - Billing and Coding: Molecular Pathology and Genetic Testing](#)

#### LCDs

[L35396 - Biomarkers for Oncology](#)

[L36715 - BRCA1 and BRCA2 Genetic Testing](#)

[L39063 - Pharmacogenomics Testing](#)

### Related National Coverage Documents

#### NCDs

[90.1 - Pharmacogenomic Testing for Warfarin Response](#)

### Public Versions

UPDATED ON	EFFECTIVE DATES	STATUS
12/03/2021	12/12/2021 - N/A	Currently in Effect (This Version)
06/19/2020	07/01/2020 - 12/11/2021	Superseded
Some older versions have been archived. Please visit the MCD Archive Site to retrieve them.		

## Keywords

N/A